

Sympathetic ophthalmia within the limit of the radical surgical recommendation - forensic implications

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Abstract: Sympathetic ophthalmia is a bilateral diffuse granulomatous inflammation of the surgical or non-surgical eye trauma that occur as a rare and severe complication of the trauma (1:14,000). The injured eye becomes the excitatory eye that initiates the inflammatory state of the non-injured eye that becomes the sympathetic eye.

The conservative therapeutic approach, i.e. the medical treatment (steroid and non steroidal anti-inflammatory therapy and immunomodulatory therapy) is recognized as the first choice compared to the radical treatment which is injured eye evisceration. However, the professional experience and the clinic evolution may play an important role. Clinical practice brings cases at the border of radical and conservative treatment with complex ethical and legal implications that are discussed. We present two cases which received a medical approach in one case and a surgical approach in other case. Based on our experience we consider that the only true prophylaxis for the loss of a healthy eye is the enucleation of the traumatized eye at the very first symptoms: many ophthalmologists share our vision. Evisceration also, in selected cases, is an acceptable alternative. We discuss also about malpraxis and liability issues of such a professional recommendation as much as ethical issues such as beneficence and non-maleficence which seems to be contradictory if we considered one eye vision or both eye vision as the best outcome.

Key Words: sympathetic ophthalmia, eye trauma, eye enucleation, eye evisceration, medical malpraxis, doctor liability.

Sympathetic ophthalmia is a bilateral granulomatous uveitis of uncertain etiology. It was first mentioned by Hippocrates, but a complete description of the symptomatology is delivered by Mackenzie towards mid 1800s [2, 4-5]. Fuchs, however, was the first who presented the histopathologic details and was able to show that this pathology can be considered a separate entity from the rest of the traumatic or inflammatory disorders of the eye [2, 6].

The etiology of this condition gives rise to several hypotheses: autoimmunity of the iris pigment, (melanin

as antigen), cellular immune response to antigens of the photoreceptor cells and genetic predisposition and oxidative stress of the photoreceptors [7-14]. The directly traumatized eye behaves as the exciting eye, while the contralateral eye becomes sympathetic to the trauma of the exciting eye and triggers a nonspecific inflammation that is characterized by the classic signs of anterior uveitis (conjunctival hyperemia, endothelial precipitates, iris nodules, synechiae), vitreitis, inflammatory chorio-retinal infiltrates (Dalen-Fuchs nodules) [15], papillitis [1-2, 9-11].

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Symptoms appear more often as a rapid response (a few days after the trauma) but sometimes as a late response, in some cases over 60, even 66 years [2, 3]. Although the condition develops as a sympathetic ophthalmia this is potentially devastating as it can affect both eyes including the non-injured eye and may lead in serious cases to a dramatic total blindness.

However, the main issues of this disease are not the symptoms or the clinical aspects, but the severity of the autoimmune response once triggered.

Although controversial, enucleation in the first two weeks after trauma may be considered by some the best prevention of the disease [1]. Recent studies show that evisceration also, in selected cases, is an acceptable alternative. In this case the choice often depends on the time elapsed since the traumatism and on the symptoms [16-18].

CASES PRESENTATION

Case 1

The first case refers to a 67-year-old male with an eye trauma „Right eye: hemophthalmos, retinal detachment, hemorrhagic choroidal detachment; left eye pterygium” (Fig. 1). A surgical treatment of retinal detachment is addressed to this eye (pars plana vitrectomy + lensectomy+ silicone oil tamponade).

Anamnesis brings informations about a fuzzy perception of light in his left eye (0.7 from normal) a few months after the trauma. Then one year later he returns to the hospital reporting new episodes of mild inflammatory episode on his left eye. At that time the right eye is disorganized, without light perception; the left eye proves stable. An evisceration of the right eye was performed. After surgery the patient reported two new inflammatory episodes, mistreated, with local and systemic antibiotherapy.

When we first met the patient he had inflammatory status of the left eye. Under local and systemic corticosteroid therapy visual acuity improved progressively In the following 5 months the patient

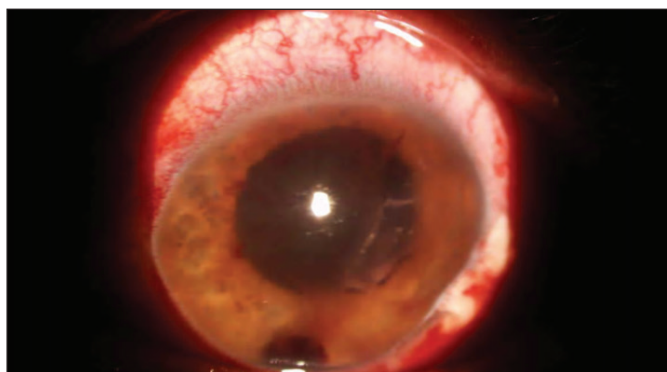


Figure 1. Ocular trauma with conjunctival hyperemia, corneal edema in all layers, paracentral corneal erosion, hyphaema, Tyndall ++, vitreous bands in the anterior chamber, iridophacodonesis, subluxated lens (from own collection).

reported one more episode of sympathetic ophthalmia. We applied a long term treatment with corticosteroid medication which was beneficial but the patient developed a subcapsular posterior cataract which we cured surgically.

Over a two-year period, up until the present, the patient is stable, under local and general anti-inflammatory steroidal support treatment.

The particularity of the case consists of the modern conservative therapeutic approach (surgical resolution for the retinal detachment and evisceration for aesthetic purposes). Despite the repeated episodes of sympathetic ophthalmia (6 in total), local and systemic steroidal and nonsteroidal anti-inflammatory drug therapy and surgical treatment of the cataract helped the patient to maintain a good, socially convenient best corrected visual acuity of 0.5 (half of the normal visual acuity).

Case 2

The second case refers to a 28 years old male patient with a 5 years extended tumoral formation in the right eye, in the iris and the ciliary body (Fig. 2). The left eye had amblyopia.

On admission the best corrected visual acuity was 20/20 on his right eye and 0.3 on his left eye.

A surgical intervention was performed and the tumor were electrically excised. Seven days after surgery the patient requests to be discharged.

Three weeks after the surgery the patient returned displaying inflammatory phenomena specific to uveitis and decreased visual acuity in the left eye. Sympathetic ophthalmia and amblyopia in the left eye was diagnosed in the left eye. Local and systemic treatment with steroids and nonsteroidal anti-inflammatories, antibiotics, mydriatic formula was started.

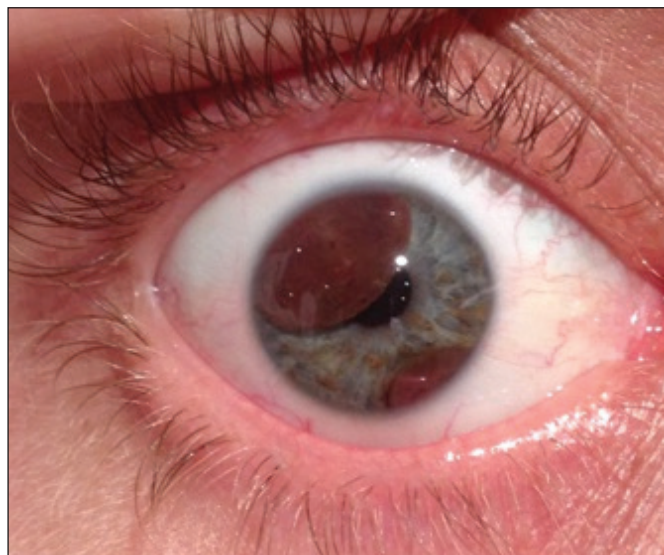


Figure 1. Ocular trauma with conjunctival hyperemia, corneal edema in all layers, paracentral corneal erosion, hyphaema, Tyndall ++, vitreous bands in the anterior chamber, iridophacodonesis, subluxated lens (from own collection).

Five days after admission the evolution was slowly favorable. However, the enucleation of the right eyeball was decided on and performed. Once the eye that had the tumor and which had undergone surgery (the exciting eye) was removed, the evolution of the left eye (the sympathizing eye) was rapidly favorable with the regression of the sympathetic ophthalmia episode and complete recovery. There were no other recorded inflammatory episodes and the patient does not require permanent anti-inflammatory medication.

DISCUSSION

Patients with sympathetic ophthalmia require often difficult decisions. On one hand interventional excess can void the recovery chances of the injured eye; on the other hand the lack of intervention may induce sympathetic ophthalmia of the congener eye and thus to generate the risk of blindness.

This disorder presents to 5 dilemmas:

1. a professional dilemma between conservative medical treatment and radical surgical treatment of the injured eye: there is not yet adopted a harmonized and standardized approach, and personal professional experience still plays a great part;

2. an ethical dilemma between beneficence (to do good) and non-maleficence (to do no harm), which in turn results in two different approaches, depending if we take into consideration just the trauma injured eye, or both eyes the injured eye and the sympathetic eye:

a. with respect to the injured eye (surgical/non-surgical injury):

I. beneficence is manifested through actions to treat and save this eye (anatomically and functionally) to cover the need of care required by this eye and fulfill the purpose of medicine, which is to prevention, diagnosis and treatment in order to restore health;

II. non-maleficence is manifested through an attempt to preserve this eye anatomically, esthetically and functionally, and these all ultimately means doing good.

b. with respect to both eyes (the injured eye and the sympathetic eye):

I. beneficence means to maximize the best long-term vision, as possible, if needed one eye vision (enucleation eventually);

II. non-maleficence is to avoid blindness.

A correct decision seems complicate from the ethical point of view because as a doctor we have to take into consideration both the eye with trauma and the vision capacity after the healing process.

A professional recommendation that takes into account the struggle to save the initially injured eye brings the risk of losing the healthy eye, a possibility of a significant loss of the visual function or even blindness, and thus it may be considered as malpractice.

On the contrary, a professional recommendation

that takes into consideration just from the beginning both eyes and to avoid blindness leans to a precece sacrifice of the injured eye in order to save ab initio the healthy: however, this means denial of needed care and unfulfilled duty of care which is in turn malpractice; it also means the loss of an organ estimated by its potential danger, which means doctor judicial liability because of the patient's permanent disability as long as it has not yet been proven that the decision to sacrifice the injured eye was real necessary.

It is known that in the dilemma between beneficence and non-maleficence, when beneficence is questionable or simply not clear, one should choose to avoid non-maleficence. "If you cannot do good, do no harm", Hippocrates, approx. 450 BC.

3. a deontological dilemma within the moral professional rules between "The health of my patient is my main duty" Declaration of Geneva, 1947, thinking to save the injured eye or the operated eye which needs medical care and "A physician shall act in the patient's best interest when providing medical care", International Code of Medical Ethics, World Medical Association, 1949, thinking at the best patient interest as the patient's well-being and this is best expressed by not being blind.

4. a legal dilemma that brings the discussion around the penal liability of the ophthalmologists, either in the event of a conservative decision, that leads to blindness or significant loss of functional vision in both eyes, or in the radical, aggressive one (enucleation of the traumatized eye) that can lead to accusations of lack of care, or abuse of surgery that is unnecessary or disproportionate to the risks (unjustified).

It may involve malpractice considered as professional conduct which, through negligence, falls below the unanimously accepted standard of skill and knowledge certified by the scientific community (e.g. the recommendation of the professional body to support saving the exciting eye through conservative treatment or, on the contrary, as the case may be, the recommendation of the professional body to support radical treatment from the very beginning); it may also be treated as criminal involvement if it is considered that the removal of the sick eye in need of care was unnecessarily performed, causing a disability which leads to a state of inferiority for the patient because of doctor's lack of competence or professional abuse.

The legal dilemma determine a legal pressure to the ophthalmologist.

Forensic reconstruction is, however, difficult because on one hand there isn't a universally accepted professional approach, just non-unitary professional recommendations (different medical schools); and on the other hand, the specialists' professional experience has a significant value that cannot be neglected at least from the perspective of the specialists' trust in their own actions (doctor's professional independence).

Enucleation must be justified. Unjustified elimination of the object of care by excess of surgery does not remove the duty of care from this case; on the contrary, because the eye might have been unnecessarily removed the duty of care might be considered unfulfilled, and turned into a permanent deficit then becomes a disability and a social handicap as well; as such, society will pay for the maintenance and support of the injured party who was put in an inferior position and the physician who caused this to happen incurs civil and criminal liability.

In the curative treatment the recommendation cannot be exceeded (i.e. one does not act beyond the therapeutic recommendation), but as long as there is a recommendation and hope of recovery or improvement, the physicians are morally obligated to fulfill the purpose of the medical act, to offer their competence and professionalism to maximize the chance that the patient only has namely if the doctor take the action: passivity, abandon or avoiding the treatment of the patient or the lack of needed cure (as by unjustified excision or removal) will undergo criticism and judicial liability for disability. Due to their professional independence, the physicians take their own therapeutic decisions that are shaped by standards, rules and recommendations connected with the specifics of the case and their professional competence, which includes their professional experience. These decisions are communicated to the patients in the process of the informed consent; if the patients endorse and authorize the medical act proposed through professional recommendation, the decision will be transferred from the physicians to themselves.

It is good to know that patient autonomy does not change or ease at all the difficulty of the professional decision or the individual, social or legal responsibility of the physicians (as might be inferred from the case of *Rogers v. Whitaker*). Failing to inform the patients is illegal and sanctionable (see the decision in the case of *Rogers v. Whitaker*); but once the informing took place by the mere knowledge of the fact that the patient has been informed, it does not reduce the responsibility of the physician for diagnosis, treatment plan or for the professional recommendation made to the patients so they can manifest their informed decision, or for the unwarranted, inappropriate, rash or risky professional decision which exposes the patients to increased risks.

A solution at least for the ethical dilemma is to create and analyze a clear risk-benefit balance: this often leads to attempting to save the injured eye or to perform the needed surgery (i.e. tumors, etc.) on the exciting eye in need of care and apply a conservative antibiotics and anti-inflammatory treatment at the onset of the ophthalmia, on the sympathetic eye but without delaying the radical intervention if the patient is non-responsive, or the radical decision when the risks of sympathetic ophthalmia become threatening.

It is difficult to decide from the beginning on the

enucleation of an eye instead of choosing first to have it treated; therefore a careful consideration that would allow a selection of cases based on the risks / benefits criterion can be a rational way to take a professional decision. Of course, once the physicians have taken a professional decision in the best interest of the patients, the latter must be notified and, based on their autonomy, this will lead towards obtaining a fully informed consent.

A complete informing process in case of surgery that aims to improve a patient's vision must include all significant risks, including the risk of blindness if this risk is materially present.

Rogers v. Whitaker case [20] is a good example: a woman in Australia suffers an eye injury at the age of nine which left her blind with one atrophic non-prosthetic eye. She wants to return to work, but for that she was asked to correct her aesthetic appearance. She decides to have her eyes examined to evaluate what can be done today in terms of technological and medical advances in the field. She is told that nothing else could be done for her to regain her permanently lost vision, but aesthetic improvements can be obtained through cosmetic plastic surgery, so a prosthesis can provide her with a more pleasant appearance. She is presented with the risks of a possible intervention, but not with the risk of sympathetic ophthalmia which can affect the healthy congener eye, which is of 1:14.000. The patient, being autonomous, accepts the physician's proposal and signs the informed consent. She undergoes surgery, but in her clinical evolution she suffers from sympathetic ophthalmia which aggravates; the patient loses her healthy eye and is left completely blind. She becomes a party in a civil lawsuit and sues the surgeon for failing to fully inform her of the risks of surgery. Insufficient information is considered to be a limitation of her freedom and autonomy, an infringement of the right to self-determination. The main question of the court was if incomplete information from the physician can be considered a breach of the duty of care and thereby a low standard of training and skill compared to other physicians, and thus representing malpractice.

There was no separate discussion regarding the criminal aspect of the blindness disability because it is included in the malpractice and the civil liability against which the doctor is held through compensation of (civil) damages, including for complete loss of vision. In his defense, the physician brings up his principle, the Bolam test which was set up many years ago after the historic case *Bolam v. Friern*, 1957 [21]: "If a physician acts as per the standard of care accepted by the professional body, he is not negligent." In this historical case it is stated that the doctor "... is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art" and that "... a man is not negligent, if is acting in accordance with such a practice, merely because there is

a body of opinion who would take a contrary view "[21].

Coming back to the Rogers v. Whitaker case, 1985, the defense uses the Bolam test and appreciates that "In short, the law imposes the duty of care: but the standard of care is a matter of medical judgment" [22].

Despite all of this, Rogers, the patient, wins the trial because the jury considers that: "The risk of total blindness, no matter how small, was material to the patient's decision and it was negligent not to advise her of the risk so that she could decide whether or not to go ahead with surgery; she wanted to see better and not to remain totally blind" [22].

In fact, not the surgery meant to treat the sequels of trauma, to improve the aesthetics of the patient, to enhance her dignity and sense of value, her chances of social integration and economic independence was considered justiciable, but the accurate process of information regarding the risks, so that by exercising their autonomy, the patients can express their decision while being fully aware of what it involves.

The doctors, however, do not know the result of the therapeutic actions that they propose (conservative or radical), nor can they provide guarantees for the results; their legal responsibility is manifested towards the means of the medical actions, and not to their results.

The best interest of the ophthalmologic patient in any situation or disease is not to remain blind (see the case of Rogers v. Whitaker, 1985), but generalizing this concept of minimizing risks can lead to the situation where the medical action, even if it is beneficent, is left without an object, which in turn means a breach of the duty of care. This feels like a limitation of morality (of good) of the medical act against the legal offensive; thus the doctors can feel frustrated in the limitation of their professional independence, competence, and self-confidence, which they could give up in order not to risk legal implications. Giving up on care is also giving up on saving a suffering eye which needs care; it means giving up on the very purpose of medicine.

Every ophthalmologist knows the implications of this type of pathology both in terms of the good will of the doctor and of the legal aspects if the outcome is unfavorable; they also know that the outcome may be twice unfavorable: (1) once if they unjustifiably lose the eye which needed care and whose care was possible with good functional prognosis in the medium and long term, (2) and the second time if they lose the healthy eye. This pressure brings into collision the principles of duty and beneficence with responsibility and liability, and this cannot always influence favorably the professional decision.

Although the best prevention of sympathetic ophthalmia is still enucleation, it gives rise to many controversies both among ophthalmologists and patients, as it constitutes a radical, and a very invasive therapy. Recent studies of Kilmartin *et al.*, show that enucleation

after a first inflammatory episode does not lead to better visual acuity, unless it is supported by a systemic anti-inflammatory steroidal therapeutic approach and immunomodulatory therapy [23]. No clinical trials were conducted; the authors described their own experience and conclusions. Makley and Azar have reached the same conclusion by choosing the systemic drug therapy conduct even in repeated episodes of sympathetic ophthalmia. The improvement of surgical techniques has led to the possibility of evisceration, not of enucleation, of the exciting or traumatized eye with the same clinical results (no episodes of sympathetic ophthalmia), but with better cosmetic results in the case of evisceration [24].

On the other hand, applying a radical therapeutic conduct from the beginning does not lead to the fulfillment of the Bolam standard and therefore to lack of civil liability as it does not have the general support of the professional body; the current international trend supports the need to try saving the injured eye, that is to take the curative and not the directly preventive approach, even if the curative one carries greater risks.

Regarding the patients whom we presented and our experience, we have tried choosing a more modern therapeutic approach adapted to each case, with the intention of optimizing the beneficence of the medical act and of minimizing the risks as per the non-maleficence criterion. Both patients were informed about their condition and both agreed to the treatment and disease management by signing informed consent forms.

Although the ophthalmic Romanian body and our own experience and opinion advocate in favor of enucleation, recent well-documented international presentations and studies made us choose in the first case the modern treatment of sympathetic ophthalmia.

In the first case we are pleased with the results, which are spectacular from the point of view of visual acuity; however, the repeated episodes of sympathetic ophthalmia after evisceration, when the support steroidal anti-inflammatory treatment is discontinued, the prolonged hospitalization and the complications lead us to believe that a radical surgical solution, namely enucleation, is the optimal professional approach.

In the second case, although initially in order to treat tumors we chose a conservative treatment (electrical excision), taking into consideration that the patient was young, had a normal visual acuity, and our surgical experience regarding iris and ciliary body tumors only gave us good results, at the first sign of sympathetic ophthalmia we decided to enucleate the traumatized eye in order to protect the healthy eye and save it from the sympathetic reaction. The results after surgery were very good, with the almost complete remission of the inflammatory episode after 4 days.

So which is then the best decision?

Should the ophthalmologists try anything that is medically possible to save the vision of the exciting eye

in need of care, looking at the beneficence for the vision of this eye and the non-maleficence as to not lose it, but accepting risks for the healthy congener eye and thus for a redoubtable pathology (sympathetic ophthalmia) that the patient did not have, did not want and the effects of which can be devastating?

Or should they give up on the treatment of the eye in need of care and also with beneficence, but for the vision within the entire visual function, and, with non-maleficence, so as to minimize the risk of blindness, to enucleate from the beginning the injured eye if the damage or injury it suffered appears to be severe, knowing that they lose the beneficence of the medical act intended to restore vision in this eye?

In other words, should they choose a curative approach that increases the risk of complications but creates an opportunity for the patient to keep the vision of the injured eye or lean towards an act that would prevent sympathetic ophthalmia and which limits the risks? Try

as much as possible to restore vision in its entirety or to settle for less, but without any risks for a good and certain functional sight? Treat within the exposure of professional competence or enucleate considering enucleation as the expression of this competence?

CONCLUSION

Although we can publish good results in treating sympathetic ophthalmia like most of colleagues, or the cure of sympathetic ophthalmia with drug therapy, we believe that, beyond ethical dilemmas and arguments that may provide a legal support, a valid professional approach is also needed and from our perspective this means that enucleation remains the best preventive treatment of sympathetic ophthalmia as it addresses the root cause and not the symptoms, and the risk of relapse is almost null.

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