Case in point: what can we learn from litigation?

Hydroxychloroquine toxicity

Being the subject of litigation is stressful and upsetting. Having to look back over your previous decisions and justify the care you delivered in good faith can be difficult. Sadly, we all live with the Sword of Damocles above us and even many years down the line our errors can come back to haunt us. As an Expert Witness it is sad to see clinicians being hauled over the coals for human errors that could happen to any of us but nonetheless still represent a breach of duty.

My Masters in Medical Law has given me an insight into the workings of the Court and primarily my duty is to that Court, regardless of my sympathy with the defendants. As part of my work I have come across cases which recur time and time again. It is heartbreaking to see patients come to harm and clinicians accused of negligence due to errors which could be so easily avoided and yet trigger a cascade of events which result in detriment to the patient.

We have a duty to patients to protect them and moreover a general duty to prevent these errors occurring throughout the NHS – sharing these cases with the readership will hopefully do that. This new regular section will focus on common themes in claims submitted to the NHS Litigation Authority (NHSLA). I personally have dealt with various cases which represent a breach of duty due to simple and avoidable errors.

Hydroxychloroquine toxicity

Hydroxychloroquine (HCQ) is a drug used in the treatment of rheumatological and dermatological disorders. Its big brother, chloroquine, used to be highly toxic, however, despite its improved safety profile retinal toxicity is a significant and potentially sight-threatening risk.

Case vignette

A 45-year-old woman was being treated with HCQ. She was taking a dosage of 400mg once daily and had been doing so for the previous seven years. She had a history of eating disorders and at presentation to the ophthalmology service her weight was 47kg.

She developed some colour vision disturbance and was referred in via her optometrist. No mention of HCQ was made in the referral and on attendance at the clinic she was not questioned on her medication despite a history of systemic lupus erythematosus (SLE) being elicited. No abnormality was detected, visual acuities were 6/6 OU and she was discharged. She re-presented three months later with vision of 6/36 OD and 6/60 OS. Hydroxychloroquine toxicity was diagnosed and the drug immediately stopped. Visual acuities recovered to 6/18 OD and 6/24 OS but no better. An internal investigation was carried out and the junior doctors undertook some training in retinal toxicity. A formal apology was issued. The patient launched legal action and a breach of duty was admitted. A significant settlement was paid out of court.

Discussion

Clearly there was a failure in not eliciting an appropriate drug history despite the fact that the patient had a history of a systemic disorder. Early toxicity can be missed and the classical Bull's eye maculopathy is a late finding. A high index of suspicion should be harboured for toxicity in patients who have been on the drug for more than five years.

Recent epidemiological studies indicate that retinal toxicity occurs in greater than 10% of patients, who have taken HCQ for over 10 years, and 20-50% of patients taking HCQ for greater than 20 years [1].

However, for patients who are treated with HCQ at the recommended dosage 5.0mg/kg measured body weight, the incidence is less than 1% at five years and only 2% at 10 years.

Therefore, the threshold dose should be calculated using actual body weight rather than ideal body weight, and the maximum safe dose is 5.0mg/kg. For example, in this case the patient should have been on a maximum of 235mg of HCQ per day. Although prescribing the drug is without an ophthalmologist's remit, it is entirely reasonable to question a sight threatening inappropriate dosing regimen in a patient who is objectively underweight.

The 2009 Royal College of Ophthalmologists Guidelines on HCQ screening advises referral to an ophthalmologist only if the patient has baseline visual impairment, eye disease confirmed by an optometrist, or if the patient notices visual symptoms [3]. Historically, patients were instructed to self-monitor with an Amsler grid, however, this practice seems to have fallen away in the UK.

The American Academy of Ophthalmology (AAO) 2016 guidelines recommend baseline ophthalmologic examination including fundoscopy with further testing if abnormalities are present at baseline, as well as annual automated central visual field testing (Humphrey 10-2), SD-OCT, and autoflourescence (AF) after five years of exposure or sooner [2].

Some patients' retinopathy progresses despite stopping treatment; involvement of the external limiting membrane on OCT carries negative prognostic value, suggestive of irreversible photoreceptor damage [4]. In high risk patients who have been on significant cumulative doses of HCQ monitoring visual acuities, 10-2 visual fields, and imaging with OCT seems prudent to try and detect toxicity early. If there is a suspicion of toxicity mutifocal ERG may be useful in determining early damage.

Learning point

If there is a suspicion of HCQ toxicity the drug should be stopped and then a formal ophthalmology evaluation should occur. Liaison with the prescribing doctor is vital to balance up the risk versus benefit profile of recommencing the drug if toxicity is not confirmed but suspected. Dosage should be correlated to weight of the patient. As ophthalmologists we have a duty to the patient and therefore if the dose of medication seems inappropriate or excessive the prescribing doctor should be informed.

References

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