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I. EXECUTIVE SUMMARY

The management of patients with ocular hypertension and primary open angle glaucoma accounts for a significant proportion of the workload of most ophthalmologists. This document should not be considered to be a protocol for management, but rather consensus guidelines that outline the definitions, epidemiology, and concepts in management of these chronic conditions. The comments expressed in these guidelines incorporate the results from recent randomised controlled trials published up to Dec 2002 as well as consensus views derived from experience where evidence from prospective trials was not available.

Low-tension (or normal tension) glaucoma is considered, for the purposes of the document, to be a subgroup of primary open angle glaucoma. Where intraocular pressure is mentioned, measurement is considered to have been with a calibrated Goldmann tonometer.

Shared care is not discussed, the reader being referred to the current guidelines published by The Royal College of Ophthalmologists on this topic.

These guidelines should be updated before June 2008 at the latest.
II. INTRODUCTION

Glaucoma causes significant visual disability in the UK, accounting for 15% of registrable blindness. This figure probably underestimates the morbidity since many patients who are eligible for registration do not appear in the statistics.

The management of patients with primary open angle glaucoma (POAG) and ocular hypertension (OHT) constitutes a major part of the workload of the general ophthalmologist. Approximately 25% of follow up attendances and 15% of new referrals either are glaucoma suspects or have glaucoma. It is estimated that there are an equal number of undiagnosed glaucoma patients in the community as there are attending eye clinics. As the population ages, case detection improves and evidence for early treatment for OHT accumulates, the number of referrals to ophthalmologists for suspect glaucoma and OHT is likely to increase.
III. OCULAR HYPERTENSION

1. Definition

Ocular hypertension (OHT) is a term reserved for eyes in which the intraocular pressure (IOP) lies above the normal population range, the optic nerve and visual field show no signs of glaucomatous damage, and there is no ocular co-morbidity. Excluded from this definition are eyes with raised IOP from demonstrable causes such as pseudoexfoliation and pigment dispersion syndrome.

Most population studies on the over 40-year age group indicate that IOPs measured with Goldmann tonometry are distributed in a manner similar to a normal distribution (mean approximately 16 mmHg). Persons with IOPs greater than two standard deviations above the mean can be labelled Ocular Hypertensive. This gives an upper limit for “normal” IOPs in Caucasians of 21 mmHg. It is of note however that this figure is statistically derived and does not imply that disease is present if measured IOP levels exceed this value.

Individuals with OHT account for 5 - 6% rather than the 2.5% that would be expected from a true normal distribution. It is becoming recognised that while these figures are true for Caucasian populations they may not hold true for other ethnic groups where the mean IOP may be lower (e.g. the Japanese are reported to have a lower mean IOP).
2. Risk factors for the development of OH

Epidemiological studies have identified those individuals in a population most at risk:

1. Increasing age
2. Individuals of black African or Caribbean origin.
3. Female gender
4. Systemic hypertension
5. Current use of oral and/or inhaled corticosteroids
6. Diabetes (especially those on insulin)
7. Family history of glaucoma

3. Management

Since elevated IOP is the major risk factor for the development of glaucomatous visual loss, finding a "raised" IOP indicates the need for further investigation and management decisions. Most ocular hypertensives are detected in optometric practice and several scenarios are possible at ophthalmological examination after referral:

1. An "unconfirmed" raised IOP at screening - the ophthalmologist finds a "normal" IOP and no evidence of any other abnormality (remember the various causes of artifactually raised IOP measurements especially “Valsalva”).

2. Intermittent OHT - raised IOP is confirmed initially but reverts to normal on repeated testing over time and no evidence of any other related abnormality is detected.

3. "Persistent" OHT where raised IOP is a constant feature.

Assuming an otherwise normal ocular examination, patients in categories 1 and 2 can be discharged and advised to seek periodic (e.g. one to two yearly) optometric re-examination. Patients in category 3 require the ophthalmologist to make a decision on the appropriate follow up and possible prophylactic treatment.
4. Risk factors for conversion to glaucoma

Estimates vary as to the conversion rate from OHT to POAG, depending on subject selection and diagnostic criteria. It is likely that approximately 10% of individuals with persistent OHT will convert to POAG over a ten-year period. Risk factors for the conversion of OHT to POAG can be divided into ocular and systemic. The most important are listed below -

A. Ocular risk factors

Height of the IOP - the greater the IOP the greater the risk

- Large vertical cup/disc ratio (indicating reduced neuroretinal rim area/volume)
- Cup/disc (C/D) ratio asymmetry >0.2
- Previous history of disc haemorrhage
- Retinal nerve fibre layer defect in the absence of morphometric optic nerve head changes
- Thinner than average central corneal thickness (note excimer laser procedures on the cornea can result in artifactualy lowered IOPs on measurement)

B. Systemic risk factors

- Increasing age
- Family history
- Individuals of black African or Caribbean origin
5. Prophylactic therapy

A decision to treat an eye with ocular hypertension should be made when the risk factor(s) present in the patient are considered to outweigh the disadvantages of treatment. Indications include the presence of signs suggestive of early glaucoma or central retinal vein occlusion in the fellow eye.

If no treatment is decided upon, two options are available to the ophthalmologist.
- Discharge to the GP with appropriate advice for follow-up in the community.
- Periodic review in the Hospital Eye service or managed shared care scheme.

The former is acceptable in low risk cases. If the latter is chosen, re-examination to assess IOP, visual field and optic disc should occur at intervals considered appropriate for the patient. Observation either in the HES or the community should employ methods sufficiently accurate and dependable to give the patient the best chance of identifying conversion to glaucoma at the earliest possible opportunity.

6. Some guidelines on treatment

When treating OHT, the aim is to lower the IOP to a level considered safe for the individual patient, and this should be at least a 20% reduction. It should be emphasised that treatment should only be advised following a careful evaluation of the full implications of treating the individual concerned, including a realistic assessment of the inconvenience and potential side effects of such treatment.

A. Treating on IOP without additional risk factors.

A constant IOP over 35 mmHg merits treatment as at these levels mechanical damage occurs to the optic nerve head. Many specialists would treat when the IOP is consistently 28-30 mmHg or above in the absence of other risk factors. The decision to initiate treatment at a lower level of IOP should be based on perceived risk by the ophthalmologist and the patient (see over).
B. Treating on raised IOP plus other risk factors.

The recently published Ocular Hypertension Treatment Study (OHTS) provides figures for risk, adjusted according to the height of the IOP, the central corneal thickness and the vertical C/D ratio. When these factors combine to give an appreciable 5-year risk of developing a significant optic disc change or a visual field defect, the ophthalmologist needs to identify this to the patient and outline the benefits and risks of treatment. This is particularly important if a decision is made to withhold treatment at this stage. The decision to treat should take into account the patient’s life expectancy and the probability of functional visual loss occurring within the patient’s lifetime.

Eyes that already possess evidence of early glaucomatous damage such as acquired neuro-retinal rim changes consistent with glaucoma, nerve fibre layer defects or abnormalities on morphometric, psychophysical or electrodiagnostic tests probably have POAG and should be treated as such (see Concepts in glaucoma management page 13).
IV. PRIMARY OPEN ANGLE GLAUCOMA (CHRONIC SIMPLE GLAUCOMA)

1. Definition

Primary open angle glaucoma (POAG) is a chronic progressive condition with characteristic changes at the optic disc (glaucomatous excavation), where it is usually possible to identify reduced visual function related to the disc changes. In most patients, the IOP is above the normal range (i.e. over 21 mmHg) at some time of the day, usually being highest in the morning. In addition, there is a gonioscopically open angle indistinguishable from normal and, in those eyes with elevated IOP, a reduced facility of outflow.

2. Prevalence and natural history

In a white population, POAG occurs in approximately 1-2% of the population over 40, increasing with age to 4% or more of the over 80-year olds. Exact prevalence rates vary depending on the criteria used for diagnosis. Left untreated, the natural history of the disease is to progress, leading to irreversible blindness. The two published population based incidence studies (from Baltimore and Melbourne) both found that about 40% of the converters had normal baseline IOPs. The Baltimore incidence study found a progressive increase in risk with increasing IOP at baseline.

3. Risk factors for the development of POAG

In addition to the risk factors already outlined for the conversion of OH to POAG, the following additional risk factors have been cited as playing a role in the development of POAG.

- Positive family history in a first degree relative
- High myopia
- Diabetes (equivocal evidence)
4. Risk factors for blindness in POAG

- Advanced disease at presentation
- Sub-optimal intraocular pressure control
- Individuals of black African or Caribbean origin
- Low socio-economic group (because of late presentation)

It is obvious that in an individual patient, the attending ophthalmologist can only influence the second of these listed risk factors. It should also be noted that some patients continue to lose vision from glaucoma despite an IOP maintained at an acceptable level.

5. Diagnosis

POAG can occur in eyes with normal or raised IOP. The concept that POAG only occurs with pressures over 21 mmHg is incorrect. Increasing emphasis has therefore been placed upon:

1. The morphological changes occurring at the optic nerve head and retinal nerve fibre layer.
2. The alterations in psychophysical tests that glaucomatous damage causes.

6. Glaucoma without field loss detected on standard automated “white on white” perimetry (SAP)

The discovery that a significant number of the optic nerve fibres can be damaged before any change is detectable in visual function by SAP has lead to the concept of "glaucoma without field loss" or “pre-perimetric glaucoma”. However other psychophysical tests such as frequency doubled perimetry (FDP) and blue on yellow perimetry (SWAP) have consistently shown that defects in visual function are present before any defect can be detected by SAP. In this condition (usually with coexistent raised IOP) there is deemed to be unequivocal evidence of glaucomatous damage to the optic nerve head +/- the nerve fibre layer. Clearly, for some patients, there is a grey area between OHT and "glaucoma without field loss".
7. Concepts in glaucoma management

The overall aim of glaucoma management is to prevent significant visual impairment within the patient’s lifetime. This will be achieved by a process of monitoring visual function with medical and/or surgical intervention when appropriate. Treatment may, therefore, not always be necessary to achieve this objective.

Despite much interest in the potential to alter the optic nerve head blood-flow, to date there is no evidence that any method of treatment other than lowering of IOP has any effect on the progression of POAG.

A. Target IOP

Management of POAG for an individual patient is helped by defining a "target IOP" for a particular eye, acknowledging that this may need to be adjusted in the light of subsequent clinical events.

The "target" IOP should be considered as the "optimum" IOP for the eye in question, and would be set at a level designed to minimise the risk of disease progression. Unfortunately, in an individual patient, there is no way of knowing the IOP level that is required to do this. However, the lower the presenting IOP and the more severe the damage at presentation, the lower the "target" IOP. Conversely, a high presenting IOP (e.g. over 40 mmHg) in conjunction with evidence of early damage may result in an initial target IOP of 20 mmHg or less. The status of the fellow eye and the patient’s life expectancy are useful guides.

The results from the Advanced Glaucoma Intervention Study (AGIS) suggest that for ‘high pressure glaucoma’ better visual field preservation is obtained when ALL IOP readings are below 18 mmHg, and with the majority below 15 mmHg. It has also been demonstrated that the IOP can rise during sleep, so attention needs to be given to those glaucoma treatments that are effective over 24 hours. There is also recent independent evidence that shows better field preservation with smaller diurnal fluctuations in IOP.
The first report from the Early Manifest Glaucoma Trial (EMGT) in Sweden has shown that, by comparison with an untreated group, in Caucasian patients with a baseline mean IOP $\leq 30$ mmHg and a baseline MD worse than 16 db, lowering IOP by 20% and to below 25 mmHg delays the onset of detectable visual field progression (in this study the mean pre and post-treatment IOPs were 20.6 and 15.5 mmHg respectively). It is relevant that this degree of IOP reduction was successful even if the baseline IOP was within the normal range. Because the rate of progression was extremely variable between individuals, it appears acceptable to observe certain patients rather than commence immediate treatment.

B. IOP monitoring.

IOPs recorded during the process of management should be considered to be measured samples of a true IOP that may be fluctuating. Before attributing too much significance to a single reading ("high" or "low"), the following factors should be considered:-

i) measurement error which may be equipment and/or patient/operator related

ii) diurnal variation

iii) compliance with medication

iv) timing of medication in relation to clinic times.

Recent evidence has suggested that IOP may rise significantly during sleep, and that this rise may be mirrored by the IOP rise that occurs after lying supine. The decision to alter medical therapy, or consider surgery to achieve the target IOP should not be taken without taking into account all available IOP data. This is particularly important if the proposed therapy carries significant risks. Similarly, a target IOP may be modified in the light of field and optic disc data acquired during the course of monitoring the patient.
8. Monitoring the patient with POAG

Sequential data are required for successful glaucoma management. The starting point is a detailed baseline assessment which under normal circumstances would include an examination of the anterior segment with a slit-lamp, at least one IOP measurement, and gonioscopy. A careful stereoscopic disc assessment through the dilated pupil and drawing (which may be usefully supplemented by disc photography +/- or digital computerised scanning of the disc/nerve fibre layer assessment) and visual field analysis completes the pre-treatment picture. Some patients will benefit from a number of pre-treatment IOP measurements and 2-3 ‘baseline’ visual fields to identify peak IOPs and establish a presenting visual performance level. Monitoring must include checking for symptoms and signs of adverse ocular and systemic reactions to therapy.

A. Frequency of monitoring

Following diagnosis, treatment is titrated to achieve the target IOP. This may require a sequence of visits in which only IOP is monitored. Once an acceptable IOP (which may not necessarily be the target IOP) has been achieved, a programme of monitoring should be instituted. The frequency of monitoring will depend on the level of IOP control achieved, the age of the patient and the severity of the disease. A sequence of 4-5 fields may be needed before reliable evidence of progression can be confirmed (see below).

It may be acceptable, under certain circumstances such as when a patient has sufficiently low IOPs following bilateral drainage surgery, to lengthen the intervals between follow-up visits considerably, or discharge the patient for review outside the Hospital Eye Service. Clearly, appropriate advice concerning review and re-referral should be given to the patient and their general practitioner/community optometrist.
B. The diagnosis of progression.

(i) Optic disc assessment.

It may be possible to identify progression by anatomical change in the optic nerve head by comparing current and previous appearances. Baseline appearance may be obtained by various means including stereophotography or computerised digital imaging. Progression may be confirmed by comparison of current status with baseline appearance. Recurrent optic disc haemorrhages are a good indicator that disease progression is occurring.

(ii) Visual field analysis.

The interpretation of sequential visual fields depends upon a number of factors:-

- the disease process itself may induce fluctuation
- the varying ability of the patient to perform the test with time
- the nature of the test (and the skill of the technician)
- the development of any coexisting disease (e.g. cataract, age related macular degeneration and diabetic retinopathy).

The identification of deterioration in a visual field generally requires several visual fields. There are a number of instruments that are appropriate for visual field assessment in POAG. Automated perimeters allow for repeated fields to be subjected to computer-assisted analysis to detect significant changes. Because of long-term fluctuation, any suspected change must be present on repeated examination. It is unusual for change due to glaucoma to be sufficiently gross that it is shown in a sequence of just two fields.

In the presence of apparently acceptable IOP control in the clinic, and a visual field and/or disc appearance that is deteriorating, it may be appropriate to perform IOP phasing to detect IOP peaks.
9. Management of the patient who demonstrates progression

In most circumstances, this will involve a change in management, particularly if it is considered that an alternative strategy will result in a lower IOP. Individual circumstances will dictate the action to be taken. Some eyes will continue to lose visual function despite lowering the IOP below the population mean by surgery. To date there has not been convincing demonstration that ‘non-IOP lowering treatments’ have a role, although it may be prudent to investigate for the possibility of severe dips in blood pressure at night in patients who are on antihypertensive medication, as such “nocturnal dipping” has been associated with glaucoma progression.

10. Normal tension glaucoma

Apart from the finding of an IOP that does not exceed 21 mmHg, this form of open angle glaucoma may be indistinguishable from its higher pressure variant.

It has been shown that central corneal thickness (CCT) may be thinner in some NTG patients compared with normal controls. This suggests that true IOP may be greater than measured IOP in some individuals with NTG.

As with POAG, it is important to be sure that the visual function and the optic disc appearance equates with a diagnosis of glaucoma, as the differential diagnosis may include space occupying intracranial lesions. Where doubt exists, the appropriate investigations should be performed.

Evidence to date indicates that reducing the IOP in the majority of patients with normal tension glaucoma will reduce the chance of disease progression, particularly if IOP is towards the upper limit of normal. Target IOPs need to be lower than in higher pressure disease and a reduction of 25-30% from baseline is needed.
V.  THE TREATMENT OF PRIMARY OPEN ANGLE GLAUCOMA

1. Medical

For most patients, this will be the first line of treatment in the attempt to achieve the target IOP. A detailed discussion of these agents is outside the scope of these guidelines.

Eye drops of first choice are now usually prostaglandin analogues or beta-blockers, with carbonic anhydrase inhibitors and alpha agonists being utilised as second choice agents. Combination therapy drops are becoming increasingly popular.

Systemic treatment for POAG is usually via carbonic anhydrase inhibitors. Long-term therapy with these agents may be necessary in refractory cases, but drug intolerance is common.

Both local and systemic anti-glaucoma drugs can have significant side effects, which may be life threatening, particularly in the elderly. A full medical and drug history may identify potential problems. Patients with allergies and dry eyes are likely to experience problems from the long-term use of topical anti-glaucoma therapy. Patients should be informed of important potential side effects when therapy is commenced. Some side effects may only appear after a prolonged period of treatment.

The side effect profile of antiglaucomatous therapy puts the onus on the prescribing ophthalmologist to be fully informed of the patient's medical and drug history and to ensure that the patient's well-being is monitored whilst under treatment.
2. Laser surgery

A. Argon laser trabeculoplasty.

Since its introduction in 1979, the published results of argon laser trabeculoplasty (ALT) have shown IOP to be reduced in most eyes with POAG, by an average IOP of 30%. It is many ophthalmologists' experience that it may be difficult to achieve this in clinical practice. In addition, there is a progressive diminution of the effect of ALT with time in some patients, and control can be lost quickly. Patients who have had this treatment should therefore be monitored more frequently than would otherwise be indicated. If subsequent drainage surgery is required, a history of ALT may increase the chance of surgical failure. However, ALT is useful in certain patients where medical therapy has failed and surgery is not possible.

B. Yag laser iridotomy.

Laser iridotomy may have a role in the absence of symptoms of intermittent angle closure but is only likely to lower the IOP in an eye with an open but narrow drainage angle where there is some iris-trabecular contact.

C. Cyclodiode laser.

In certain patients, usually those in whom other modalities of therapy have failed, partial cycloablative therapy with trans-scleral (or endoscopic) diode laser may be indicated.

3. Surgery

Since the late 1960's, the operation of choice in POAG has been a "trabeculectomy" Modifications to the size and shape of scleral flap and internal osteum have not been associated with reduced success rates. The use of laser suture lysis, releasable sutures and postoperative bleb manipulation have been introduced to reduce the early failure rate and postoperative morbidity associated with this type of glaucoma filtration surgery.
Those eyes at risk of later failure due to scarring of the drainage bleb should be considered for antimetabolite supplementation. Risk factors for late failure include previous ocular surgery, a long pre-operative history using certain topical medications, black African or Caribbean origin, pre-existing uveitis and diabetes mellitus (particularly with retinopathy). The optimum anti-metabolite regime for each individual will vary, and caution should be used when utilising these agents, particularly those with high potency. Referral of individuals at high risk of failure to a glaucoma specialist should be considered.

A. Glaucoma in the presence of cataract.

For the patient with glaucoma controlled on a simple topical medication regimen who requires cataract surgery, cataract extraction with implant can be performed with continuation of topical medications as appropriate postoperatively. In some patients, cataract surgery may be associated with a fall in IOP and a trial off a pre-operative medication can be a sensible strategy. For the patient who requires drainage surgery but who also has cataract, a combined cataract extraction, implant and trabeculectomy procedure should be considered. Phaco-trabeculectomy (in which phacoemulsification and lens implantation is combined with drainage surgery) has the convenience to the patient of a single operation but may not produce the same IOP reduction as a trabeculectomy procedure alone.

B. Risks of filtering surgery.

Patients should be informed of the potential complications of filtering surgery prior to any surgical procedure being performed. Specific mention should be made of the increased risk of cataract (found in all the recently published prospective trials) and the long-term risk of blebitis and endophthalmitis, which is greater when antimetabolites are used.
C. Non-penetrating surgery such as viscocanalostomy and deep sclerectomy

At the present time there is insufficient evidence from prospective studies that these operations have a lower incidence of long-term complications while maintaining good IOP control to advocate their use in routine glaucoma practice.

D. Surgery for complicated cases.

Patients with multiple risk factors for failure of conventional drainage surgery, or in whom there is no unscarred conjunctiva available at the superior limbus, usually require alternative strategies for reducing IOP. Such complicated cases are best managed by consultants specialising in glaucoma.
VI. SOCIAL AND PRACTICAL ASPECTS OF GLAUCOMA

1. Information concerning drop utilisation

It is the prescriber's responsibility to ascertain that the patient understands details of acquisition, storage and usage of their antiglaucomatous medications, including how and when to deliver them to the eye.

2. Registration as partially sighted and legally blind

It is appropriate to discuss with the patient the advantages of registration should their disease severity be sufficient to render them eligible for registration. Other eye disease may lower the threshold of eligibility.

3. Glaucoma and driving

Ophthalmologists should ascertain the driving status of any patient in whom they suspect an inability to pass the driving regulations. Individuals who have field defects in both eyes and/or who have acuity suspected of falling below the legal limits for driving should be informed that it is their legal obligation to inform the DVLA of their ophthalmic diagnoses.

4. Informing relatives of their risk of glaucoma

There is evidence that first-degree relatives, and in particular siblings, of glaucoma patients have a significantly increased risk of glaucoma within their lifetime. Ophthalmologists should inform a patient with glaucoma of this and give advice concerning contacting relatives to advise them of their increased risk and the advisability of attending an appropriate practitioner for screening.
5. Help agencies and glaucoma

A number of agencies may provide support to the patient with glaucoma. When appropriate, ophthalmologists should inform their patients of the existence of such agencies and provide contact details.

Such agencies include:-

- The International Glaucoma Association (IGA)
- Royal National Institute for the Blind (RNIB)

6. Utilisation of written information

A number of agencies provide useful information by means of handouts. Ophthalmic departments should consider utilising such handouts or designing their own for the benefit of patients with glaucoma and their carers.
VII. REFERENCES


VIII. WORKING PARTY AND ACKNOWLEDGEMENTS

The first College Glaucoma and OHT guidelines (1997) were produced by a Working Party with the following members:

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