Complete Summary

GUIDELINE TITLE

Diabetic retinopathy.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Retina Panel, Preferred Practice Patterns Committee. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 33 p. [98 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Ophthalmology (AAO), Preferred Practice Patterns Committee, Retina Panel. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 1998. 32 p.

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetic retinopathy

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Ophthalmology

INTENDED USERS

Health Plans
Physicians

GUIDELINE OBJECTIVE(S)

To prevent, retard, or reverse visual loss, thereby maintaining or improving vision-related quality of life by addressing the following goals:

- Identify patients at risk of developing diabetic retinopathy
- Encourage involvement of the patient and primary care physician in the management of the patient's systemic disorder, with specific attention to control of blood sugar (hemoglobin A1c), serum lipids, and blood pressure
- Encourage and provide lifelong evaluation of retinopathy progression
- Treat patients at risk for visual loss from diabetic retinopathy
- Minimize the side effects of treatment that might adversely affect the patient's vision and/or vision-related quality of life
- Provide visual rehabilitation for patients with visual loss from the disease or refer for visual rehabilitation

TARGET POPULATION

Persons with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Comprehensive adult medical eye evaluation
2. Medical history, including duration of disease, history of glycemia control, and medications
3. Examination, including best-corrected visual acuity, intraocular pressure, gonioscopy, slit-lamp biomicroscopy, dilated fundoscopy including stereoscopic examination of the posterior pole, and examination of the peripheral retina and vitreous
4. Ancillary tests, including color fundus photography, fluorescein angiography, ultrasonography, and optical coherence tomography

Treatment

1. Laser photocoagulation surgery (scatter, focal, or grid)
2. Color fundus photography

3. Fluorescein angiography
4. Other treatments, including intravitreal administration of corticosteroids, protein kinase C inhibitors, and growth hormone antagonists, which are currently under investigation and are not currently recommended
5. Vitrectomy

Management

1. Follow-up care of patient
2. Referral if appropriate
3. Patient education

MAJOR OUTCOMES CONSIDERED

Patient outcome criteria include:

- Visual function
- Vision-related quality of life
- Coordination of care management to achieve optimal glycemic control

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A detailed literature search of articles in the English language was conducted on the subject of diabetic retinopathy for the years 1997 to 2002.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ratings of Strength of Evidence

I. Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

II. Level II includes evidence obtained from the following:
    - Well-designed controlled trials without randomization

- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

III. Level III includes evidence obtained from one of the following:
- Descriptive studies
- Case reports
- Reports of expert committees/organization
- Expert opinion (e.g., Preferred Practice Pattern panel consensus)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of diabetic retinopathy were reviewed by the Retina Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of Importance to Care Process

Level A, most important
Level B, moderately important
Level C, relevant but not critical

COST ANALYSIS

Computer-simulation models have been designed to predict the medical and economic effects of applying accepted methods for controlling diabetic retinopathy among type 1 patients. In one study, recommendations for screening were taken from the Public Health Committee of the American Academy of Ophthalmology. Surgery recommendations and modeled treatment efficacy were drawn from the reports of the Diabetic Retinopathy Study (DRS) and the Early Treatment Diabetic Retinopathy Study (ETDRS). Costs of screening and surgery were drawn from published Medicare reimbursement data.

The model predicted that over their lifetime, 72% of type 1 patients will eventually develop proliferative diabetic retinopathy (PDR) requiring panretinal photocoagulation and that 42% will develop macular edema. If treatments are delivered as recommended in the clinical trials, the model predicted a cost of $966 per person-year of vision saved from proliferative diabetic retinopathy and $1120 per person-year of central visual acuity saved from macular edema. In addition, if all type 1 patients received eye care at federal expense, the predicted savings exceed $167.0 million and 79,236 person-years of sight. These costs are less than the cost of a year of Social Security disability payments for those disabled by vision loss. Therefore, treatment yields a substantial savings compared with the direct cost to society of the case of an untreated type 1 patient. The indirect costs, in lost productivity and human suffering, are even greater.

A more recent analysis, using the same computer model, predicted the cost-effectiveness of detecting and treating diabetic retinopathy from the insurers' perspective. Screening and treatment of eye disease in diabetic patients costs, on average, $3,190 per quality-adjusted life-year (QALY) saved. For patients with type 1 diabetes, it costs $1,996 per QALY saved; for patients with type 2 diabetes who use insulin, it costs $2,933 per QALY saved; and for patients with type 2 diabetes who do not use insulin, it costs $3,530 per QALY saved.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2003). All *Preferred Practice Patterns* are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The ratings of importance to the care process, (A, B, C) and the ratings for strength of evidence, (I, II, III) are defined at the end of the "Major Recommendations" field.

Diagnosis

The initial examination for a patient with diabetes mellitus includes all features of the comprehensive adult medical eye evaluation, with particular attention to those aspects relevant to diabetic retinopathy.

History

An initial history should consider the following elements:

- Duration of diabetes [A:I]
- Past glycemic control (hemoglobin A_{1c}) [A:I]
- Medications [A:III]
- Medical history (e.g., onset of puberty, [A:III] obesity, [A:III] renal disease, [A:II] systemic hypertension, [A:I] serum lipid levels, [A:II] pregnancy [A:I])

Examination

The initial examination should include the following elements:

- Best-corrected visual acuity [A:I]
- Intraocular pressure [A:III]
- Gonioscopy when indicated [A:III]
- Slit-lamp biomicroscopy [A:III]
- Dilated funduscopy including stereoscopic examination of the posterior pole [A:I]
- Examination of the peripheral retina and vitreous [A:III]

Slit-lamp biomicroscopy with accessory lenses is the recommended method to evaluate retinopathy in the posterior pole and midperipheral retina. [A:III] The examination of the peripheral retina is best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens. [A:III]

Examination Schedule

Recommended Eye Examination Schedule for Patients with Diabetes Mellitus

Diabetes Type	Recommended Time of First Examination	Recommended Follow-up*
Type 1	5 years after onset [A:II]	Yearly [A:II]
Type 2	At time of diagnosis [A:II]	Yearly [A:II]
Prior to pregnancy (type 1 or type 2)	Prior to conception or early in the first trimester [A:I]	No retinopathy to mild or moderate nonproliferative diabetic retinopathy (NPDR): every 3-12 months [A:I] Severe NPDR or worse: every 1-3 months [A:I]

***Abnormal findings may dictate more frequent follow-up examinations.**

Treatment

Management recommendations for patients with diabetic retinopathy are summarized in the table below.

Management Recommendations for Patients with Diabetes

Severity of Retinopathy	Presence of clinically significant macular edema (CSME[1])	Follow-up (Months)	Scatter (Panretinal) Laser	Fluorescein Angiography	Focal Laser[2]
1. Normal or minimal NPDR	No	12	No	No	No
2. Mild to moderate NPDR	No Yes	6-12 2-4	No No	No Usually	No Usually[1, 3]
3. Severe or very severe NPDR	No Yes	2-4 2-4	Sometimes[4] Sometimes[4]	Rarely Usually	No Usually[5]
4. Non-high-risk PDR	No Yes	2-4 2-4	Sometimes[4] Sometimes[4]	Rarely Usually	No Usually[3]
5. High-risk PDR	No Yes	3-4 3-4	Usually Usually	Rarely Usually	No Usually[5]
6. High-risk PDR not amenable to photocoagulation (e.g., media opacities)	--	1-6	Not Possible[6]	Occasionally	Not Possible[6]

1. Exceptions include: hypertension or fluid retention associated with heart failure, renal failure, pregnancy, or any other causes that may aggravate macular edema. Deferral of photocoagulation for a brief period of medical treatment may be considered in these cases. Also, deferral of CSME treatment is an option when the center of the macula is not involved, visual acuity is excellent, close follow-up is possible, and the patient understands the risks.
2. Focal photocoagulation refers to direct focal laser to leaking microaneurysms or a grid photocoagulation pattern to areas of diffuse leakage or nonperfusion seen on fluorescein angiography.

3. Deferring focal photocoagulation for CSME is an option when the center of the macula is not involved, visual acuity is excellent, close follow-up is possible, and the patient understands the risks. However, initiation of treatment with focal photocoagulation should also be considered because, although treatment with focal photocoagulation is less likely to improve the vision, it is more likely to stabilize the current visual acuity.
4. Scatter (panretinal) photocoagulation surgery may be considered as patients approach high-risk PDR. The benefit of early scatter photocoagulation at the severe nonproliferative or worse stage of retinopathy is greater in patients with type 2 diabetes than in those with type 1. Treatment should be considered for patients with severe NPDR and type 2 diabetes. Other factors, such as poor compliance with follow-up, impending cataract extraction or pregnancy, and status of the fellow eye will help in determining the timing of the scatter photocoagulation.
5. Some experts feel that it is preferable to perform focal photocoagulation first, prior to scatter photocoagulation, to minimize scatter laser-induced exacerbation of the macular edema.
6. Vitrectomy is indicated in selected cases.

Follow-up

The follow-up evaluation includes a history and examination.

History

A follow-up history should include changes in the following:

- Symptoms [A:III]
- Systemic status (pregnancy, blood pressure, renal status) [A:III]
- Glycemic status (hemoglobin A_{1c}) [A:I]

Examination

A follow-up examination should include the following elements:

- Visual acuity [A:I]
- Intraocular pressure [A:III]
- Slit-lamp biomicroscopy with iris examination [A:II]
- Gonioscopy (if iris neovascularization is suspected or present or if intraocular pressure is increased) [A:II]
- Stereo examination of the posterior pole with dilation of the pupils [A:I]
- Peripheral retina and vitreous examination, when indicated [A:II]

Recommended intervals for follow-up are given in the above table.

Provider

Because of the complexities of the diagnosis and surgery for PDR, the ophthalmologist caring for patients with this condition should be familiar with the specific recommendations of the Diabetic Retinopathy Study (DRS), Early Treatment Diabetic Retinopathy Study (ETDRS), United Kingdom Prospective

Diabetes Study (UKPDS), and Diabetes Control and Complications Trial (DCCT). [A:III] The ophthalmologist should also have training in and experience with the management of this particular condition. [A:III]

Counseling/Referral

Patient education about the importance of maintaining near-normal glucose levels and near-normal blood pressure and lowering serum lipid levels is an important aspect of the care process. [A:III]

Patients with diabetes mellitus without diabetic retinopathy should be encouraged to have annual dilated eye examinations to detect the onset of diabetic retinopathy. [A:III] Patients should also be informed that effective treatment for diabetic retinopathy depends on timely intervention, despite good vision and no ocular symptoms. [A:III]

Those patients whose conditions fail to respond to surgery and those for whom further treatment is unavailable should be provided with proper professional support and offered referral for counseling, vision rehabilitation, or social services as appropriate. [A:III]

Definitions:

Ratings of Importance to Care Process

Level A, most important
Level B, moderately important
Level C, relevant but not critical

Ratings of Strength of Evidence

I. Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.
II. Level II includes evidence obtained from the following:
    - Well-designed controlled trials without randomization
    - Well-designed cohort or case-control analytic studies, preferably from more than one center
    - Multiple-time series with or without the intervention
III. Level III includes evidence obtained from one of the following:
    - Descriptive studies
    - Case reports
    - Reports of expert committees/organization
    - Expert opinion (e.g., Preferred Practice Pattern panel consensus)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations.")

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective evaluation and management of diabetic retinopathy resulting in prevention, retardation, or reversal of visual loss and improved vision-related quality of life

POTENTIAL HARMS

Focal Laser Photocoagulation for Diabetic Macular Edema

Focal laser photocoagulation for diabetic macular edema may result in an initial decrease in central vision. Patients undergoing this treatment should be informed of this possibility. Rarely, this treatment may induce subretinal fibrosis with choroidal neovascularization (CNV), which may be associated with permanent central vision loss. The most important factors associated with subretinal fibrosis include the most severe degree of subretinal hard exudates in the macula and elevated serum lipids prior to laser photocoagulation. Only 8% of cases of subretinal fibrosis were directly related to focal laser photocoagulation. Laser photocoagulation causes disruption of the retina with destruction of the photoreceptors. In cases where laser burns have been placed close to the fovea, especially burns that are confluent, the patient may be aware of paracentral scotomas. In addition, inadvertent foveal burns may produce a permanent central scotoma. It is important to avoid placing laser burns in or close to the center of the fovea.

Scatter Photocoagulation for Severe Nonproliferative Diabetic Retinopathy (NPDR) or Proliferative Diabetic Retinopathy (PDR)

Scatter treatment was shown in the Diabetic Retinopathy Study (DRS) to result in some central vision loss. Peripheral visual field constrictions with poor dark adaptation are side effects of extensive scatter photocoagulation treatment. In the presence of neovascularization, the patient should be warned that vitreous hemorrhage may occur during the course of scatter laser photocoagulation.

Vitrectomy

Vitreous surgery has the potential for serious complications, including recurrent vitreous hemorrhage, retinal detachment, and rubeosis iridis, and these complications may result in severe visual loss and eye pain.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these Preferred Practice Patterns will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients´ needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.
- Preferred Practice Patterns are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Retina Panel, Preferred Practice Patterns Committee. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 33 p. [98 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Sep (revised 2003)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology

GUIDELINE COMMITTEE

Preferred Practice Patterns Committee, Retina Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Retina Panel Members: Emily Y. Chew, MD (*Chair*); William E. Benson, MD; H. Culver Boldt, MD; Tom S. Chang, MD; Louis A. Lobes, Jr., MD; Joan W. Miller, MD; Timothy G. Murray, MD; Marco A. Zarbin, MD, PhD; Leslie Hyman, PhD (*Methodologist*)

Preferred Practice Patterns Committee Members: Joseph Caprioli, MD (*Chair*); J. Bronwyn Bateman, MD; Emily Y. Chew, MD; Douglas E. Gaasterland, MD; Sid Mandelbaum, MD; Samuel Masket, MD; Alice Y. Matoba, MD; Donald S. Fong, MD, MPH

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

No proprietary interests were disclosed by members of the Preferred Practice Patterns Retina Panel for the past 3 years up to and including June 2003 for product, investment, or consulting services regarding the equipment, process, or products presented or competing equipment, process, or products presented.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2006 Nov. 21 p.

Available in Portable Document Format (PDF) from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

PATIENT RESOURCES

The following patient education booklet is available:

- Diabetic retinopathy (2001)

The following patient education brochure is available:

- Diabetic retinopathy (1998)
- Diabetic Retinopathy (Spanish: Retinopatia Diabetica) (1998).

The following patient education videotape is available:

- Diabetic retinopathy (1990)

Print copies: Available from the American Academy of Ophthalmology (AAO), P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By

providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on February 20, 1999. The information was verified by the guideline developer on April 23, 1999. This summary was updated again on April 30, 2004. The information was verified by the guideline developer May 20, 2004.

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