RANZCO THE LEADERS IN EYE CARE

The Royal Australian and New Zealand College of Ophthalmologists

Fluorescein and Indocyanine Green Angiography Guidelines

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Introduction and purpose

These Guidelines have been issued by RANZCO for the guidance of ophthalmologists. They should not be used by any other persons or provided to patients as a replacement for medical advice.

1. Fluorescein angiography (FA) is an extremely useful and minimally invasive diagnostic investigation that is frequently performed in ophthalmologists' private practices and ophthalmology departments. Indocyanine Green (ICG) angiography is a similar but less frequently performed investigation. Despite the generally low risks of the procedure, deaths have occurred during and following FA in both Australia and overseas.

General

2. Guidelines in eye care are neither minimal nor aspirational but represent quality eye care commensurate with knowledge as at the date of issue. These Guidelines are based on the best available scientific data and on the collective judgement and evaluation of available evidence by retinal specialists in consultation with medico legal and medical (immunology) colleagues.

3. The Guidelines are for the pattern-of-practice rather than the care of a particular individual. While they may meet the needs of most patients, they cannot possibly meet the needs of all patients.

4. Adherence to these Guidelines will not ensure a successful outcome in every situation and the Guidelines 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.

Patient information prior to Fluorescein and Indocyanine Green Angiography

5. The actual information provided to patients prior to FA, and the method of communication of this information, is at the discretion of the individual practitioner. It is considered that the following information is essential:

    - The reason for the FA being performed
    - A description of the procedure
    - A description of potential risks of FA

6. As a general rule, written information is a helpful adjunct to any verbal explanation and increases retention of information by patients. A sample information sheet and consent

form for FA is included with these Guidelines. The information may be added to at the discretion of practitioners.

Note: If ICG Angiography is to be used, appropriate modification should be made to the sample FA information sheet/consent form (see paragraph 17).

Informed Consent

7. FA is an invasive procedure that carries a small but definite risk of serious adverse effects including anaphylaxis and death. Informed consent is mandatory for such procedures. While there is no specific legal requirement for written informed consent, it is considered best medical practice to document such consent in the patient's medical record, and consent forms are a useful aid in the documentation process.

Procedure

8. The procedure of FA is well described in the literature and is beyond the scope of this document. The supervising medical practitioner may elect to delegate part/s of the procedure to appropriately trained personnel, but responsibility for the welfare of the patient remains with the practitioner.

Probability of adverse events

9. All ophthalmologists should be aware of the probability of adverse events in order to make informed decisions on the procedure. The following information has been obtained from the published literature.[1-4]

Common reactions[1-4,7,8]

10. Nausea (2 to 3 per 100)

    Vomiting (1 to 2 per 100)

    Urticaria/pruritus (3 to 5 per 1000)

    Vasovagal reaction – low - reliable estimates not available

    Injection site complications – low - reliable estimates not available

Uncommon reactions

11. Severe reactions – anaphylaxis, severe asthma/bronchospasm, cardiac arrhythmia, myocardial infarction, cardiac arrest, seizure (1:1,900 – 1:18,000)

    Death (1:50,000 to 1:222,000)

Management of adverse events

12. Detailed management of all potential adverse events is beyond the scope of this document. RANZCO considers that the following are the minimum requirements for a practice or facility performing ophthalmic angiography:

    - Staff trained in the recognition and management of adverse reactions including anaphylaxis and cardiopulmonary arrest
    - Regular updating and practice of staff in techniques of cardiopulmonary resuscitation
    - Equipment and medications to manage minor and major reactions, including anaphylaxis and cardiac arrest
    - A protocol for contacting Emergency Services in the event of a severe adverse event

Reporting of adverse events

13. RANZCO encourages Fellows to report serious adverse reactions to intravenous fluorescein and/or ICG to ADRAC (the Adverse Drug Reaction Advisory Committee) using the form available online at http://www.tga.gov.au/form/blue-card-adverse-reaction-reporting-form.

Fluorescein Angiography in "high risk" patients

14. Recognition of patients at high risk of anaphylactic reactions should be based on a careful history, particularly drug history and past history of anaphylaxis and significant drug reactions. Skin testing has not been shown to be of value in evaluating the risks of anaphylactic reactions to FA, and is not considered necessary prior to patients undergoing this procedure. An adverse reaction to prior FA is highly predictive of further adverse reactions.[4]

15. Patients with a history of severe adverse reaction to fluorescein, in whom further FA is considered medically essential, may require consultation with other medical colleagues, consideration of performing the angiogram in a hospital setting, and premedication to decrease the risk of hypersensitivity reactions. Successful desensitisation to fluorescein has been reported [5], and this should only be considered in consultation with an experienced immunologist / allergist.

Fluorescein Angiography during pregnancy

16. FA is generally avoided in patients known to be pregnant, although no definite teratogenic or other adverse effects on the unborn child have been documented as a result of FA[6]. In certain circumstances it may be necessary to perform FA during pregnancy if it is felt that it

is absolutely required, to allow treatment of sight threatening conditions, and there is no alternative.

Indocyanine Green Angiography

17. Patient information, consent and the precautions for ICG angiography are similar to those outlined for FA. The incidence of nausea and vomiting appears to be less with ICG than fluorescein. As the ICG preparation used for angiography contains iodine, allergy to iodine is considered a relative contraindication to ICG angiography. Caution is advised when performing angiography in patients with diabetes and renal impairment who are on metformin. If possible they should not take metformin the morning of the procedure.

References

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4. Kwiteroich KA, Maguire MG, Murphy RP, Schachat AP et al. Frequency of adverse reactions after fluorescein angiography. Ophthalmol 1991; 98: 1139-42.

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Record of Amendments

Page	Details of amendment	Date approved
Entire document	Wording of paragraphs 6 and 17 and page 6 updated	03/06/2015

SAMPLE FLUORESCEIN ANGIOGRAPHY INFORMATION SHEET AND CONSENT FORM

What is Fluorescein Angiography?

Fluorescein angiography is a photographic test of the retina, the 'film' in the back of the eye. A water soluble dye called fluorescein is injected into a vein in your arm, where it travels through the body reaching the eye. A special camera is used to take multiple photographs of the back of your eyes as the dye passes through the blood vessels, providing information about the retina and nearby tissues. Depending on the procedure employed, this may involve bright flashes of light.

Why is Fluorescein Angiography performed?

Fluorescein angiography is used to diagnose certain eye conditions, determine if treatment is possible, and plan or guide treatment. Common conditions requiring fluorescein angiography include diabetic retinopathy, macular degeneration, and retinal vascular diseases. In some cases, the angiogram may need to be repeated to monitor your response to treatment or changes in your eye condition.

What are the side effects of Fluorescein Angiography?

After fluorescein angiography, your skin will turn yellow for several hours. This will fade as the dye is filtered out by the kidneys – this leads to the urine turning a dark yellow-orange colour for up to 24 hours. Your vision will be blurred and you should not drive for at least four hours after the angiogram, but there is no permanent effect on the vision from having the test done.

Are there any risks?

Fluorescein angiography is a safe and very helpful test. Thousands of fluorescein angiograms are performed every year in Australia and New Zealand. The chance of adverse effects is low, but as with any medical procedure there are some risks involved. Some patients experience nausea during the angiogram, which usually passes within seconds. Some patients may vomit. Occasionally some fluorescein will leak from a fragile vein, which may cause a localised burning feeling and yellow staining of the skin. The burning usually lasts a few minutes and the staining takes a few days to disappear.

Some patients may experience allergic reactions to the fluorescein dye. The most frequent allergic reaction is a skin rash, which is often itchy and may appear within minutes after the fluorescein injection. More severe allergic reactions are fortunately rare.

The most severe allergic reaction is called anaphylaxis, which is rare but may be life threatening. Very rarely patients may experience breathing difficulty or heart rhythm disturbances, which can be severe and even cause death. If you feel any itching, tingling in the lips or tongue, difficulty breathing or pain during or after the angiogram, let us know

immediately. You may require medication to control the reaction, and your condition will be monitored until it has resolved. Delayed reactions are very uncommon, but it is important that you tell us if you experience any delayed effects that you feel may be related to your fluorescein angiogram.

Other information

It is very important for you to tell us about any health conditions that you have, all the medications that you are taking, and especially any allergies to medications that you have had in the past. It is preferred that you bring this information as a letter from your doctor. If you have had a previous fluorescein angiogram, please let us know. You do not need to fast for this test.

Fluorescein is reported to be safe in pregnancy, but we prefer to avoid this test in pregnant patients if possible. Please advise if you are pregnant, or suspect you could be pregnant.

If you have any further questions or concerns, please ask us before you have your angiogram.

CONSENT TO FLUORESCEIN ANGIOGRAPHY

I, _____ have read, or have had read to me, the above information concerning the procedure of fluorescein angiography. I understand this information, and any questions that I have asked have been answered to my satisfaction.

I consent to the procedure being performed _____

Witness _____

Date / /