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Contrast Media and Risk Management: Develop Simple Rules of Conduct

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Inherent in any technique of direct opacification (e.g. angiography), the injection of a contrast medium is common during routine examinations such as CT and MRI. The advantage of this injection is to improve the circulator y system and various organs, and thus help to individualise and characterise pathologies. Accidents, although rare and even exceptional for the most serious (i.e. death), are well documented. Risk factors are known, even if we know that certain reactions, including serious ones, are unpredictable.

T he injection step is never trivial and remains a critical step for teams. Awareness of the risk, embedded in medical imaging, should facilitate management. Management is to know, prevent and organise, which implies, given the complexity of clinical situations and the different levels of education of stakeholders, proposing simple rules of conduct and ensuring that they are understood.

Main Risks

We distinguish schematically immediate manifestations, namely allergic reactions, which are quite common, and delayed reactions such as secondary renal failure due to iodinated contrast agents (techniques using x-rays) and the now well understood occurrence of nephrogenic systemic fibrosis after the injection of gadolinium contrast (MRI). The goal here is not to detail the various risks and how to prevent them individually, but to list solutions aiming to mitigate these risks.

Prerequisites

These focus on knowledge and organisations. The messages are:

• Have a good overall knowledge of the risks associated with the use of contrast agents and more specifically those using specific molecules or those with specific uses (e.g. the intrathecal injection);

• Ensure knowledge is constantly updated. Good site management is to individualise the thematic contrast agents, and to agree on the name of a referring physician specifically in charge of monitoring the subject. The web accessibility of the recommendations of professional groups and societies not only greatly facilitates the monitoring process but the scalability of data from year to year is also faster;

• Be trained in the identification, characterisation, staging (classification by Ring and Messmer (1977) and the control of intolerance reactions. On site scenarios are useful. Medical and non-medical staff should regularly receive practical training in the management of life-threatening emergencies. There is also labelled training for the staff of health facilities to qualify for a certificate valid for four years (French decree of 3 March 2006 on the certification of training actions and emergency care), such as training focused on accidents with contrast agents proposed during the French Days of Radiology;

• Provide comprehensive, consistent and frequently and regularly verified support material, contained in a trolley in healthcare facilities or a briefcase in an office. This equipment must be easily accessible, located in a central position, a place known to all staff, not locked but not open to the public. The verification of material is to ensure that, in relation to a predetermined list, the content is complete, and expiration dates are checked. The division of roles in the audit of the trolley must be established: we could for example do a check ever y day, per formed by the potential users of the trolley (it is a way for them to know the content), with a logbook and also spot checks by the quality manager. It should also be clear about what action to take when using the equipment: update content, and then close with a small plastic seal - both show that a check was conducted and dissuade people from taking from this pseudo reserve. The promotion of the use of serum histamine and tryptase to characterise allergic reactions also calls for sampling kits to be made available with this equipment;

• Have effective means of communication (telephone with emergency numbers marked on or in the immediate vicinity of telephones, intercom), simple procedures (such as the code blue used in the U.S. for major emergencies) and defined procedures with external stakeholders (call an intensivist or emergency ambulance service) etc.;

• Display reminders of practical action in an immediate emergency as well as details on specific tasks: circuit blood samples to characterise an allergic reaction and make an appointment with the specialist allergist;

• Provide training for new personnel (medical and non-medical) upon taking up their post. Also, locums arriving on site must inquire about the means at their disposal and the plan put in place in case of an emergency.

Risk Management Throughout the Stages of the Examination

1. Making appointments

• Provide a framework so staff can easily identify, depending on the content of the application, the examinations for which an injection is needed. This pre-decision determines the later stages of the planning, is usually carried out by non-medical staff and will be reassessed when the patient is present;

• Be able to identify patients at risk of allergic reaction, the key question being whether there has been an intolerance reaction during a previous exposure to a contrast agent. A simple question such as: "Have you ever had a CT scan? An MRI? Did it go well? " will address the issue without creating anxiety;

• Be a ble t o i dentif y p atients who warrant a dosage of creatinine, whether for a CT scan (risk of renal failure) or MRI (risk of nephrogenic fibrosis, varied depending on the products used). Attitudes can be systematic for all patients, or on demand for financial reasons, particularly for outpatients and to exclude the use of risky products (hyperosmolar iodinated products and unsubstituted linear gadolinium). This is all based on risk factors collected at the patient interview and / or on forms filled out by applicants (patients older than 70 years, diabetics, history of renal disease, renal surgery, proteinuria, gout, heart failure, etc.). Access to a recent dose (less than two months or less than six weeks unless there is clinical deterioration in the meantime) will also limit withdrawals;

• Ban fasting, antinomic with the protection to be provided by adequate hydration (prevention of secondary kidney disease from iodinated contrast agents);

• Arrange appointments for injections when medical staff will be present;

• Do not expose the patient to repeated injections and so organise, when possible, the care of the patient in one sitting (the concept of a one-stop shop, unfortunately not valued by the French pricing system);

• In the event of necessary consecutive injections, ensure an appropriate interval adapted to the dose used, the renal function and the clinical situation (in a patient with normal renal function, rely on a half- life of around two hours for non-specific products).

2. Receiving and preparing the patient

• Check that the risk factors were investigated;

• Take them into account and, if necessary, challenge the injection: exploit the results of creatinine to express them as G FR (glomerular filtration rate) estimated by the MDRD formula*. If necessary and if it has not already been done, find a substitution for another examination or correct any dehydration (protocols for rapid rehydration, delaying the procedure by less than an hour, are now available);

• Look into possible treatment with beta-blockers, knowing that it is a complicating factor in treatment of shock if it occurs. Similarly, identify the base blood pressure so vital signs can be interpreted under emergency conditions.

3. Carrying out the protocol and performing the act

• Use a licensed product suitable for the intended use (type, concentration), taking into account the potential risk factors of the patient;

• In the event that uncertainty remains on the characterisation of a prior reaction and where the examination could not be deferred, change the product;

• Use the minimum dose required for the diagnosis (and thus adjust the dose to the patient);

• Indicate the product and the dose used, and the batch number;

• Ensure that a doctor prepares the products used intrathecally (there is no room for error given the risks specific to certain products and stringent aseptic objectives).

3. Patient monitoring

• There should always be two carers, including a doctor close to the patient during injection: a nurse, familiar with the site, who knows how to provide immediate relief and call alerts, and a doctor ready to intervene. This doctor is not necessarily a radiologist and may be an accident and emergency doctor (a solution adopted in teleradiology);

• Ensure attentive monitoring during the critical phase that covers at least the first 15 minutes after the injection.

The patient should remain in a medical establishment for at least 30 minutes after an injection. In the case of hospitalisation, this precaution is automatically respected but for outpatients, it might be necessary to make them wait before allowing them leave.

4. Accident

• Identify it and act quickly;

• Remember to note the start time;

• Implement appropriate treatment;

• In the event of an allergic reaction, run blood samples as quickly as possible and organise consultation by a specialist allergist who can make recommendations for formal eviction or contrast agents to which the patient proves to be allergic.

5. The report

• Specifies the data on the contrast used (type and dose), states observed intolerance reactions, the people involved and successful management. The report is indeed an essential tool for traceability, simple letters being more randomly integrated into the patient's record.

• For patients with complex allergic histories, it is also important after a successful examination to include that tolerance was good without clinical intervention.

Concluding Messages

The relevance of the examination

It goes without saying that with respect to a risk review, the relevance (justification) of the latter has been verified. In case of complications, it is one of the first questions that will be raised.

Patient information

Risk management obviously involves much patient information on the risks they are exposed to, when it is requested by the clinician and making the appointment. The appointment stage is often too late to give the patient the freedom to abandon or at least postpone the examination.

The overzealous The unjustified refusal of the examination: Taking into account the potential nephrotoxicity of contrast sometimes leads to extreme positions, not taking into account that, in assessing the risk / benefit ratio, denying or deferring an examination or to only perform it without contrast can be just as detrimental to the patient. For intravenous injections there is a risk threshold of glomerular filtration rate (GFR) estimated by the MDRD formula within 45 ml/min/1.73m2. It is only above this threshold that it is recommended to search for an alternative technique, or if the indication is maintained, volume expansion and hydration. Case by case discussion with a kidney specialist as well as the patient must always be preferred to discharging a patient.

The untimely interruption of treatment: In intravenous use, stopping metformin is now only proposed for a GFR less than 45 ml/min/1.73m2.

Using MRI is also a risk

Allergic reactions, sometimes severe, initially discovered with iodine products, may also occur in MRI. The risk is even more important as this technique, erroneously, has a reputation for being harmless, but the scanner, increased physical isolation (narrow tunnel, room door tightly closed) and the length of acquisition makes patient monitoring more difficult. Hence the importance of quality audio and video communications, solutions such as alarms and, if necessary, the real-time monitoring of vital signs.

The harmonisation of terminologies

The presentation of risk levels would benefit from being standardised, the frequency of reported effects on the basis of pharma covigilance data, as specified by the following harmonisation proposals. “ An undesirable side effect is:

• Very common if the frequency is ≥ 10%

• Frequent if the frequency is ≥ 1% and <10%

• Uncommon if the frequency is ≥ 0.1% and <1%

• Rare if the frequency is between ≥ 0.01% and <0.1%

• Ver y rare if the frequency is <0.01%.”

Risk orphans

We must not forget the undesirable side effects related to the osmotic load of iodinated contrast agents (ensure to seek a prior pulmonary sub-oedema by cuts without injection during the exploration of dyspnea), iodine residues contained in the iodinated contrast product vials (an inappropriate injection in cases of hyperthyroidism), as well as the precautions to be taken during pregnancy.

* The MDRD (Modification of Diet in Renal Disease) equation allows calculation of the estimated glomerular filtration rate (GFR) from serum creatinine.

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