CONTINUING EDUCATION PROGRAM: FOCUS...

Spinal injections: Medico-legal and insurance considerations

V. Hazebroucq\textsuperscript{a,*,b}

\textsuperscript{a} Agence régionale de santé d’Île-de-France, 35, rue de la Gare, 75019 Paris, France
\textsuperscript{b} Université Paris-Descartes, 75006 Paris, France

KEYWORDS
Interventional radiology; Injection; Insurance; Medical responsibility; Medico-legal

Abstract
A series of serious accidents following spinal, cervical and lumbar foraminal injections has led French medical insurers to start discussions with professional radiologists to ask us to take the necessary measures allowing them to continue to cover the exceptional but considerable risks of these interventional radiology procedures. This article summarises the facts and the insurers’ recommendations and insists on the need to adopt a new and permanent strategy to improve the quality and safety of our practice.
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For several decades now, insurers who guarantee medical responsibility have been emphasizing the increase in the cost of claims, due to the combined progressive increase in the frequency of accidents declared, complaints and claims (on average about +3.8% per year for the last 20 years, i.e. the number of cases over this period has doubled, (Fig. 1), and above all, in the recent greater increase in the awards made by the courts\textsuperscript{1}. The statistics for accidents declared in recent years to Sou Médical-MACSF (French insurers for the medical profession) actually show a significant increase in the declaration of accidents concerning osteoarticular interventions: whereas until 2000 the main at-risk imaging activity was vascular imaging (ignoring diagnostic errors, anaphylactic reactions relating to contrast agents and falling from the examination table), this now only represents a tenth of the number of declarations of osteoarticular incidents and accidents — declared by

\* Agence régionale de santé d’Île-de-France, 35, rue de la Gare, 75019 Paris, France.
E-mail address: vhazebroucq@gmail.com

\textsuperscript{1} According to the annual reports for 2009 and previous years of the Sou Médical-MACS group, the costs of a single case may currently exceed 7 to 9 million euros for a major disability where provision must be made for continuous care over several decades; this amount must be put into perspective with the annual premium which a doctor can pay and the frequency of accidents, approximately 1.66 each year per 100 medical practitioners). For radiology, the annual overall rate of claims is around five per 100 radiology practitioners, if diagnostic errors, complications of radiology procedures and various physical injuries, e.g. falls in the radiology unit, are included.

2211-5684/S – see front matter © 2012 Published by Elsevier Masson SAS on behalf of the Éditions françaises de radiologie.
http://dx.doi.org/10.1016/j.diii.2012.07.012
various medical and surgical specialists: radiologists, rheumatologists, anaesthetists and pain specialists, neurosurgeons, orthopaedic and rehabilitation specialists etc. Where the spine is concerned, accidental complications may be very serious (tetraplegia, paraplegia or death of the patient), although these procedures, which are presented as simple and safe, are very widely practised in many public and private centres, and in extremely variable conditions. Several recent articles published all at about the same time have questioned these procedures:

- some of the accidents recorded by the Sou Médical-MACSF have given rise to a French publication in European Radiology [1], one of the authors of which has also published a clarification in which he openly questions whether intraspinal injections should continue to be offered — and/or practised [2];
- we have known for several years, moreover, that certain long-acting corticosteroids (including Hexatrine [triamcinolone]), formerly used for intradiscal injection therapy, have been abandoned for these indications after reports of the secondary appearance of disabling spinal canal calcifications [3];
- two publications in 2009 in the prestigious New England Journal of Medicine (NEJM) [4,5] are not devoid of medico-legal interest. They concerned two randomised trials corroborating each other, which concluded that the efficacy of vertebroplasty for the analgesic management of osteoporotic vertebral compression was no greater than that of placebo. An editorial by the same authors [6] following from these publications in the Medical Journal of Australia seriously questioned this practice, considered to be ineffective and potentially dangerous, and concluded that it would, without doubt, be better to establish the efficacy and safety of our radiological procedures before generalising them in routine clinical practice. It is true that there are no precautions similar to the marketing authorisation for medicinal products or medical devices for therapeutic or diagnostic procedures; once a technique has been described, it can spread immediately, even without its efficacy and risks being properly evaluated.

The two NEJM papers (Kallmes et al. & Buchbinder et al.) were widely contested and criticised, particularly in a letter to the editor refused by the NEJM but published in January 2010 in the journal of the Canadian Association of Radiologists. They were subsequently put into perspective by the appearance of several later studies objectively more favourable to these interventional procedures, including a Belgian-Dutch randomised study (Vertos II) published in various journals including the Lancet in August 2010 [7], which demonstrated, unlike the two NEJM series, that certain patients undeniably benefited in the long term from vertebroplasty correctly performed at the right time. This paper was accompanied by a commentary summarising all the randomised studies on kyphoplasty and vertebroplasty known in August 2010, and announcing publication in the near future of new studies, which it was hoped, would show sufficient corroboration to settle the question [8].

What should be borne in mind here is that the description of a small series of serious accidents occurred at the same time as this series of papers, resulting in the medical committee of Sou Médical-MACSF contacting representatives of radiology professionals at the beginning of 2010 to study together the precautions which might guarantee that these interventional procedures could continue to be insured and avoid an uncontrolled increase in the cost of claims, leading interventional radiology into the same difficult situation as gynaecology/obstetrics with regard to antenatal ultrasonography. As soon as it was informed of this, the French Society of Radiology (SFR), via its Interventional Radiology Federation (FRI), wished to deal with the matter in order to avoid the insurers deciding unilaterally to no longer insure these practices for fear of being unable to cope with the financial

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**Figure 1.** Claims statistics recorded by Sou Médical-MACSF. Source: Revue Responsabilité de la Macsf-Sou médical, November 2011, Rapport Annuel 2010 supplement.
costs which could result from an unchecked increase in these new risks. Work described below, was therefore started, with several specific organ radiological societies contributing to it along with the FRI, and needs to be finalised as quickly as possible.

While waiting for the results, in the summer of 2010, Sou Médical-MACSF decided, as a precaution, during the regular re-evaluation of its risks, to exclude certain osteoarticular procedures — now classified among the "practices with a significant or increased potential risk" [9] – from its basic professional third party insurance contracts.

This decision applies to new members of the scheme and to existing members asking to update their insurance cover.

The procedures concerned are foraminal injection into the cervico-dorso-lumbar spine, vertebroplasty, kyphoplasty and cementoplasty, as well as shoulder capsule dilatations. These risks can still be covered case by case, on condition that they are specifically declared and that evidence is provided of sufficient training and appropriate material conditions.

There are two areas where progress is essential straight-away: firstly more and better information needs to be given to our patients in order to obtain informed consent for this type of procedure; and secondly, our indications for interventional radiology need to be more robust.

Improving and giving more information to our patients to obtain informed consent

There are still too many examples of patients referred to the radiology unit for spinal injection who have understood (or remembered) the referring clinician to have told them that they will just have "a little radiologically-guided needle prick to inject the right medicinal product, at just the right dose into the right place", that "this process is perfectly harmless and almost painless", and "that it will avoid the unpleasantness of systemic treatment or surgery, without any risk." Of course, that is not all entirely untrue... nor perfectly correct, but it is now certain that the lack of complete truthfulness of this presentation would be considered as a fault by a judge in the event of complications and would almost automatically result in the court awarding payment of damages, even if the procedure were perfectly indicated and performed under optimal technical conditions.

In future, the clinician and the interventional radiologist (ideally together, since it is specified that the final responsibility for informing the patient rests mainly on the person performing the procedure, i.e. the radiologist) must take care to inform the patient in detail of the nature of the procedure, its real usefulness (immediate and long-term effect), its risks, even the serious ones, whenever they can be said to be normally predictable (and paraplegia following foraminal injection, while exceptional, is now legally speaking "normally predictable") as well as of other therapeutic solutions that could be envisaged, and finally of the consequences in the event of refusal.

As an illustration, proposing vertebroplasty following osteoporotic compression should include the explicit information that several recent papers, published in a major English language journal, have concluded that the effect of this procedure is no better than placebo, but that these articles have been contradicted by other scientific publications, of at least comparable status. A copy of these papers could even be offered to those of our patients likely to understand them, or to their general practitioner, so that they could discuss it with him or her, making it clear to them that they have been offered this procedure nevertheless for such-and-such a medical reason and that they must consider it in complete freedom and make the decision themselves.

" Doubtless, some practitioners will wish to object that this "unsalesman-like" presentation may encourage patients to choose to decline the offer. That is indeed their right, and our objective should not be to convince the patient to undergo a procedure that judges will necessarily tend to consider a "comfort operation" with essentially an analgesic purpose, and for which there is no real vital or emergency necessity, while incurring the risk (slight but established) of a compressive haematomata in the spinal canal, which could adversely affect the patient's neurological status [10].

Let us add that obviously the doctor must keep the evidence showing that he has actually provided this detailed information, during a previous meeting with the patient, and that the latter has had a sufficient period for reflection before agreeing to the procedure and undergoing it.

Simply handing out a standardised form explaining the procedure and obtaining consent, in return for a signature, will be considered by the judge as an attempt to obtain release from responsibility to protect the doctor, rather than to inform the patient and allow him to fully exercise his choice of what should be done with his own body. As is perfectly natural, the law and the courts require an explanation of the procedure and its indication specifically suited to the patient in question, which should be entered in writing in the patient’s records, or in a letter addressed to the referring clinician and to the patient’s general practitioner, following a preliminary consultation sufficiently prior to the procedure for the patient to have time to reflect on it. Ideally, this letter or consultation report will be dictated in front of the patient, specifying this in the document.

Improving the robustness of our indications for interventional radiology

The time when an indication was rapidly agreed in a phone call between the radiologist and the patient’s general practitioner or specialist is long past. A real preliminary consultation, free or otherwise, seems to be essential in order to study the radiological information and confirm with the patient the indication put forward by the referring clinician. As for informed consent, a written record of these discussions will need to be kept, specifying that "the indication for the procedure is necessary given the failure of other treatments", or that "all other medication, including opioids, have proved insufficient for providing the patient with relief", or even whether the patient has put forward personal or professional reasons for expressly requesting this procedure, etc.
In the medium term, we are asked to implement the following additional proposals, many of which are fortunately widely applied, and:

- classify our interventional radiology procedures into three levels of complexity according to their risk, and the infrastructure and expertise necessary to perform them safely:
  - everyday procedures, which form part of a general radiologist’s normal practice,
  - intermediate procedures, that should only be undertaken by specialist radiologists, in a still relatively large number of radiology centres (outpatient or hospital units), with a technical environment to be specified, doubtless intermediate between the equipment of a standard radiology practice and that of an operating theatre. The French National Authority for Health (Haute Autorité de Santé - HAS) published an evaluation report in December 2010, which is yet to be implemented [11],
  - ultra-specialised procedures, the most delicate and/or those with the greatest risks and which will need to be limited to a small number of referral centres (public or private), doubtless with particularly well equipped technical facilities and situated close to all the amenities which might be necessary to deal with any complication (intensive care, surgery etc.);

- define precisely the interventional radiology frameworks necessary for performing procedures in each of these three categories: premises, equipment and procedures necessary for performing the treatment and for managing possible complications. For example, for procedures where there is a risk of paraplegia or tetraplegia, we need to anticipate the possibility of rapid intervention being required to relieve the compression caused by an intraspinal haematoma (i.e. whether a neurosurgeon or an orthopaedic surgeon specialising in the spine is in the vicinity);

- propose objective criteria for evaluating skills for specialist doctors authorised to practice intermediate or more specialised procedures: initial training (DIU [Inter-University Diploma], training courses, minimum number of procedures performed under the guidance of a senior specialist, etc.), regular participation in staff meetings and the activities of a referral centre, in-service training, and maintenance of skills by regularly practising a sufficient number of procedures. This must all be anticipated without creating a threshold effect which could spur certain colleagues into thoughtlessly increasing their indications so as not to drop below the crucial limit: whereas in obstetric ultrasonography, a pregnancy cannot be invented in a woman who is not pregnant, there is indeed possibly more risk of too easily proposing an injection in patients complaining of back pain;

- strengthen our scientific methodology to define and set the indications for these procedures, in order to avoid the patient and the radiologist finding themselves in the radiology room after an indication decided by the referring clinician, without any real possibility of re-discussing the indication: for everyday procedures, one prior consultation at least will henceforth be necessary, which could however be delegated (as anaesthetists regularly do for pre-anaesthesia consultations), and for more specialised procedures, there should be a multidisciplinary discussion allowing the different management possibilities, radiological or otherwise, to be considered. Ideally, in referral centres, the majority if not all of the specialists who may contribute to the management of this type of patient should take part in these discussions: rheumatologists, spinal orthopaedic surgeons or neurosurgeons, anaesthesiologists or pain specialists and functional re-education specialists, neurologists, etc. ;

- reformulate the information to be given to our patients to obtain informed consent. According to HAS recommendations, the information sheets should be validated in tests involving patient associations and should be updated whenever there is a new fact, such as publication in the literature of a previously unknown complication or, as in the example of vertebroplasty, a negative reassessment of the benefits of a commonly practised procedure;

- help ensure that these procedures are systematically recorded by Registre Épidémiologique de la Fédération de Radiologie Interventionnelle (EPIFRI) (a French group observing interventional radiology), so that exhaustive information can be provided, globally and for each practitioner, on the number of procedures performed, the proportion and type of people involved in undertaking them, the indications, the results and any complications observed;

- publish recommendations for the practice of interventional radiology: beyond the guide currently being prepared under the auspices of the SFR and the FRI, it has been suggested that we should envisage the publication later of good practices, established according to the methodology validated by the HAS;

- supplement the hygiene and prevention of infection recommendations relating to treatment to establish rules suitable for our procedures2, our installations and equipment, not always as easy to decontaminate as an operating theatre: consider, for example, an ultrasound ventilation unit3;

- in addition, Sou Médical-MACSF is envisaging eventually only providing insurance cover for the most risky pro-

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2 For example, some protocols require the radiologist who gives an injection into a shoulder to wear a cap and mask, but do not require the patient to do the same. It should be noted here that an SFR hygieneworking group has been formed under the chairmanship of Prof. Francis Joffre in which the French Society of Hospital Hygiene is taking part. A first scientific meeting on this subject took place during the French Radiology Days in October 2010. Recommendations are to be prepared, with the methodological support of the HAS, the results of which are awaited by the insurers. The experts will then be able to use these recommendations to say whether normally required precautions were observed if a procedure is unfortunately followed by an infectious complication, or whether negligence can be determined due to non observance of the professional recommendations.

3 Certain hospital protocols, sometimes boldly transposed from surgery to radiology by the CLIN (centres for action against nosocomial infections) leave one perplexed as to the level of evidence and the feasibility of their requirements: for example, there is a recommendation to outpatients stating that two hours before an interventional radiology procedure they should take a full shower at home using Betadine and rinsing with sterile water, without telling them to then put on clean clothes.
procedures to practitioners who undertake the professional accreditation process for at-risk practices and agree to observe all the professional recommendations published by the SFR;

• finally, on the methodological level, Prof. René Amalberti, who advises both Sou Médical-MACSF and the HAS on management strategy and prevention of medical risks, invites our profession to stabilise our recommendations of good practice for at-risk procedures over minimum periods of four or five years (except for the duly recognised exception which proves the rule), in order to allow management of the rules for preventing undesirable events to be standardised at national level. This supposes that all progress occurring between the appearance of a recommendation and the following five-yearly update is to be considered and strictly evaluated, as are biomedical research protocols. According to this eminent expert in risk management, this would be the only rational, reasonable way of limiting the multiplication of variants of procedures that anyone might think of and lay claim to—often in good faith, despite a lack of scientific or statistical demonstration valid in a court of law—saying that his technique is obviously the best and that others who have made a different choice are incapable.

The number and scope of these requirements may seem considerable, even "over the top" to those of us who still believe that (a) excellent initial training of members of the profession and (b) suitable regulations, reinforced by (c) damage indemnities and (d) sanctioning of faults, and (e) the awareness and conscientiousness of members of the health profession should be enough to ensure the quality and safety of treatment. Experience demonstrates each day that this is not enough, and that it is high time to envisage abandoning the paradigm of individual guilt in favour of new reasoning based on the systemic pursuit of quality and safety of treatment. Two important reports by the British National Health Service and the Institute of Medicine of the National Academy of Sciences of the United States set out the reasons [12,13].

The organisation of our structures and activity must be founded a priori on the principle made popular in Latin from the times of ancient Rome by Lucius Seneca, "To err is human" ("Errare humanum est"), more recently reformulated in 1949 in English by Edward Aloysius Murphy, an American aeronautics engineer: "If anything can go wrong, it will". Consequently, we should now organise ourselves to:

• plan for multiple safety processes and tools for continuously evaluating the quality and safety of practices and results;

• continuously detect where we are dysfunctioning, correct these situations and evaluate the real efficacy of these corrections, according to the PDCA (Plan-Do-Check-Act) principle of the Deming cycle;

• regularly inform the profession and the public of what is continually being done to guarantee quality and safety and thus merit confidence.

Our profession collectively has work to do; without doubt we need to produce an order of priority for dealing with these requirements over time, without however delaying, and we must establish an undeniable level of professionalism for this interventional activity. It must be done without being needlessly maximalist and avoid imposing on us intolerable or excessively expensive demands for the simplest and most commonplace procedures, or unreasonably minimalistic by adopting recommendations too out of line with those of the learned societies of other disciplines or specialities which practice similar procedures (anaesthetists and pain specialists, rheumatologists, orthopaedic surgeons and neurosurgeons, etc.).

Throughout this work SFR members will be able to count on the informed advice of our insurers and particularly of Sou Médical-MACSF, as well as, in hospitals insured by the Société Hospitalière d’Assurances Mutuelles (SHAM). On their medical boards these specialist insurers have practitioners from many disciplines, who understand perfectly the evolution of complications declared by their members as well as the opinions of experts analysing the procedures during judicial processes. In a recent clarification of these questions, Dr Thierry Farman also emphasized his wish for learned societies to contribute to providing a better definition of the skills and qualifications of experts who may be asked to explain aspects to insurers, to regional commissions for conciliation and compensation of medical accidents (CRCI) and to courts, as it seems that the quality of current experts is too variable and random [14].

Disclosure of interest

The author declares that he has no conflicts of interest concerning this article.

References


[9] Personal communication of 18 October 2007 with Mr Thierry Rodier, Medical Risk Department of the Sou Médical-MACSF.


[14] Invitation lecture given during the 1st Congress on « Pédagogie des Nouvelles Techniques Interventionnelles » [Teaching Minimally Invasive Therapies], Clermont-Ferrand, 28th March 2012, entitled ”What the insurers find”. 