Original Article

Practice Patterns of Informed Consent Before Contrast Dye Administration in Spine Radiology: A Cross-Sectional Study

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Abstract

Background: Contrast media are frequently used in spine radiology for improving the quality of images obtained by means of magnetic resonance imaging (MRI and computed tomographyCT scans. However, contrast media can cause allergic reactions, nephrotoxicity and, more rarely, other systemic complications. For this reason, administration of contrast media requires prior informed consent which must be provided in accordance with the ethical principles of medical practice and with the relevant legal requirements. In clinical practice, however, there is considerable variability in the way in which informed consent is obtained and recorded. the objective is to assess practice patterns of informed consent before contrast dye administration in spine radiology and to assess compliance with established standards. **Material and Methods:** A hospital-based cross-sectional study was conducted to include 312 patients of spine imaging using contrast dye. The data were obtained by using a structured questionnaire and by auditing the patients' medical records. The variables studied were type of consent, information given to the patient, patients' understanding and documentation. The data thus obtained were analyzed using descriptive and inferential statistics. **Results:** Among the patients studied, 58.3% of them received a written consent for the administration of contrast dye. However, 41.7% of them were given consent verbally. Furthermore, 46.8% of patients stated that they were completely informed of the risks and alternatives of the use of contrast dye for their spinal images. Documentation of pre-contrast assessment of renal function was found in 72.1% of cases. The presence of institutional protocols was significantly associated with the quality of consent (p value < 0.05). **Conclusion:** Large numbers of patients undergoing contrast-enhanced spine imaging are not receiving adequate informed consent. Efforts to standardize the processes of obtaining and documenting informed consent, as well as improving patient education, are required to address these issues and improve the safety of patients.

Keywords: Spine radiology, contrast media, informed consent, MRI, patient safety, cross-sectional study.

Received: 03 June 2026 **Revised: 21 June 2026** **Accepted: 06 July 2026** **Published: 09 July 2026**

Introduction

Contrast agents are widely used in spine radiology to evaluate for infection, tumor, postoperative changes, and inflammation. The use of contrast enhanced MRI and CT has been shown to improve diagnostic accuracy for a variety of conditions, when compared to non-contrast studies.[1,2] However, the use of contrast agents for radiologic studies has associated risks, and therefore careful selection of patients and pre-procedural counseling of potential risks is essential.[3]

Informed consent for any medical procedure or test is required and must be communicated to the patient. The information that must be communicated to the patient includes a description of the proposed procedure or test, the purpose for which it is to be conducted, the benefits and any associated risks and alternatives that are available. A description of the potential risks and complications of contrast material administration, as well as alternatives for the proposed imaging study, must be communicated to the patient.[4] In the event that the patient has any questions or expresses any concern about any aspect of the procedure or test, every effort must be made to provide a clear explanation of the information in a manner that is understandable to the patient. In the case where contrast material is to be administered as part of a radiologic imaging procedure, every effort must be made to obtain the patient's consent for the proposed study and for the use of contrast material prior to the administration of the contrast material.[5-7]

Informed consent for imaging using contrast agents to evaluate infections and/or tumors of the spine and to evaluate post-operative changes and other conditions where inflammation or infection may be a concern is not always given with the best of intentions. It is generally documented and given in an inconsistent manner. Inadequate informed consent for the use of contrast dye may occur as a result of a variety of factors, including lack of time, pressure from rapid work flow, a lack of protocol or guidelines for the process, or failure to follow established guidelines.[8-11]

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DOI:
10.21276/amit.2026.v13.i2.815

How to cite this article: Raithatha NR, Ravankolkar KK, Raiththa PP. Practice Patterns of Informed Consent Before Contrast Dye Administration in Spine Radiology: A Cross-Sectional Study. Acta Med Int. 2026;13(2):XX-XX.

The indications for the use of contrast in spine radiology are often for diagnosing infections or tumors. Given the emergent nature of these conditions, a process of obtaining informed consent for contrast dye administration is often abbreviated. In addition, many patients who receive spine imaging have varying degrees of health literacy, which affects the process of obtaining informed consent.[13]

While it is important to obtain consent for contrast dye administration, it is not enough to merely document that consent has been obtained. Many patients do not have a complete understanding of the procedures and associated risks that are being consented for.[14,15] Additionally, the practice of documenting consent for contrast dye administration varies widely between institutions. Some practices obtain only verbal consent while others require written documentation.[16]

The use of contrast media in radiographic assessment of the spine is widespread. Increasing numbers of studies are using contrast media in a variety of different scenarios. Informed consent before the administration of contrast media is an ethical medical practice. It is essential to assess current practice and establish the extent to which informed consent is currently used in the radiographic assessment of the spine and to establish the scope for future improvement.[17–21]

Materials and Methods

The study is a cross-sectional study, carried out in the radiology department of a tertiary care teaching hospital, conducted over a period of 6 months. All adult patients having contrast- enhanced spine imaging either by means of MRI or CT scans were included in the study. Total number of patients included in the study were 312. Patients were selected by means of convenience sampling. Sufficient number of patients belonging to all age groups and having different reasons for the requested spine imaging studies were included in the study.

Patients with emergency situations (where the patient is unable to give consent due to unconsciousness or similar reasons) and critically ill patients were excluded from this study. Patients who refused to participate in this study were also not included in the study. Ethical approval was obtained from the Institutional Review Board (IRB) of the University, and all the participants were explained the objectives of the study. They were also told that their participation in the study was voluntary and that they could withdraw from the study at any time without any fear of prejudice. All the patients who agreed to participate in the study signed an informed consent form.

During data collection patients were interviewed with a structured questionnaire to assess their knowledge and understanding of the use of contrast media and of the risks associated with it as well as their degree of satisfaction with the consent process. Moreover, Medical records of patients were reviewed to assess the type of consent that was given (written or verbal), the information that was provided to the patient, the degree of understanding of the information provided by the patient as well as the documentation of other relevant information such as the renal function of the patient, allergies, etc. and the physician's notes.

The main variables studied in the current study were the type of consent given to patients, whether written or verbal, the extent of information given to patients, and the quality of documentation of the consent process. The secondary variables studied variables in this study were the demographic data of the patients, the reasons for the imaging studies performed on them, and the practices of the institution. All the data were entered into a computer software package for analysis using descriptive statistics in the form of frequency and percentage for the studied variables.

Inferential statistical analysis were conducted to establish relationship between variables including consent type and patient understanding. Chi-square test were calculated and a p-value less than 0.05 was considered statistically significant. The study aimed to critically evaluate the existing practice of obtaining consent for CE spine imaging and to establish the need for intervention to overcome any of the identified gaps in practice.

Results

The demographic data of the included study participants are presented in this section. The majority of the study participants were of middle age and 48.7% were between 31 and 50 years of age. This is the typical age group of patients with degenerative or pathological spine conditions that require imaging studies. The gender distribution of the participants was relatively even and slightly male dominated. Demographic characteristics of the study participants are important to note, because patients' age and gender could affect how easily patients are to explain the consent process to and to engage in it. For example, older patients may require more explanation because of their comorbid conditions and the risks of contrast agents.

Table 1: Demographic Characteristics of Participants

Variable	Frequency (n=312)	Percentage (%)
Age 18–30	78	25.0
Age 31–50	142	45.5
Age >50	92	29.5
Male	168	53.8
Female	144	46.2

Table 2: Type of Informed Consent Obtained

Consent Type	Frequency	Percentage (%)
Written Consent	182	58.3
Verbal Consent	130	41.7

The findings indicate that while written consent was obtained in the majority of cases, a substantial proportion of patients relied solely on verbal consent. This raises concerns regarding documentation and medico-legal protection, as written consent is generally considered more reliable evidence of patient agreement. The high prevalence of verbal consent may reflect workflow constraints or lack of standardized protocols. It also suggests potential variability in institutional practices, highlighting the need for clear guidelines to ensure consistency and accountability.

Table 3: Information Provided to Patients

Information Component	Provided (%)
Purpose of contrast	78.5
Risks explained	46.8
Alternatives discussed	32.1
Opportunity for questions	55.4

This table illustrates gaps in the quality of information provided to patients. While most patients were informed about the purpose of contrast use, less than half received adequate information about potential risks. Even fewer were informed about alternative imaging options. This suggests that the consent process may be more procedural than informative, limiting patient autonomy. The relatively moderate percentage of patients given an opportunity to ask questions indicates partial engagement, but there remains significant room for improvement in patient-centered communication.

Table 4: Documentation and Safety Measures

Parameter	Documented (%)
Renal function test	72.1
Allergy history	64.7
Consent documentation	58.3

Documentation of safety measures such as renal function assessment and allergy history was observed in a majority of cases, reflecting awareness of contrast-related risks among healthcare providers. However, the documentation of consent itself was comparatively lower, indicating a discrepancy between clinical safety practices and ethical/legal documentation. This gap may expose institutions to medico-legal challenges and underscores the importance of integrating consent documentation into routine workflows.

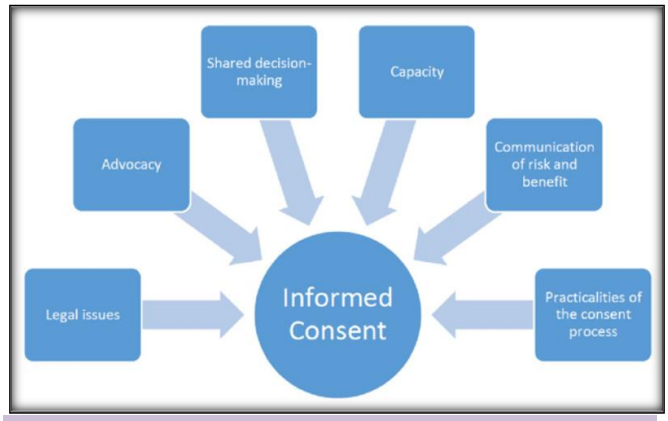

Figure 1: Overall Quality of Informed Consent Practices

Discussion

The study demonstrated significant variability in practice prior to the administration of contrast agent for contrast enhanced spine radiology imaging. Despite the wide spread use of contrast enhanced imaging, the process of obtaining informed consent is not optimal and remains variable.[1,4] Although written consent forms were completed for the majority of patients, many patients received contrast agent with verbal consent for imaging. In some instances, patients received limited information regarding the risks and alternatives for the procedure.

A low percentage of patients received complete information on risks and alternatives. Thus, even though contrast enhanced imaging is frequently used for assessment of the spine, the process of obtaining informed consent for these studies is suboptimal. The results of this study are consistent with prior studies of lack of patient education for radiologic procedures.[8,14] Thus, it appears that the process of obtaining informed consent for many patients is more of a formality rather than a process that allows patients to make fully informed decisions.

While documentation of the patient's renal function and allergy history, and thus clinical safety practices, adhered to existing guidelines,[5,6] this does, however, reveal a disconnect between those practices that are part and parcel of everyday clinical practice and those which are part of a more ethical oriented practice that is currently not integrated into workflow on a routine basis.[9,16]

Institutional factors that determine the way consent for imaging is obtained, seem to play a larger role than patient factors. However, the existence of such protocols and their implementation is largely up to the individual facility. Facilities with established protocols for contrast media-containing imaging studies were more likely to comply with guidelines for obtaining informed consent.[11,17] Thus, the development and implementation of such institutional guidelines is crucial for ensuring that all patients receive the same level of information regarding the imaging that is to be performed.

Patient factors also need to be taken into account when seeking informed consent, not least the health literacy of the patient, and their level of anxiety. A previous study has identified that patients have limited understanding of their medical treatment,

especially where this treatment involves complex terms and procedures used by health care providers.[13,15] This underlines the need for all patient information to be written in the simplest language possible and for the use of appropriate visual aids to assist the patient's understanding.

It also has important medico-legal implications, because a lack of adequate documentation of informed consent given for CT scans could put the healthcare provider at risk of being sued, particularly in cases of contrast induced adverse reactions.[10,18] Therefore documenting the informed consent process is not only ethical but also a legal matter.

Gaps identified in the current study are not unique to this country or region, and in fact are characteristic of radiology practices worldwide.[19,20] Implementation of standardized consent practices, utilizing tools such as structured consent forms or checklists, has the potential to significantly improve practice compliance and enhance patient satisfaction.[21]

The study points out too many facets to be addressed to overcome the issues in obtaining informed consent for Contrast Enhanced Spine Imaging. Education of all stakeholders, implementation of policy at all levels and systems interventions would be required to overcome these many problems.

Conclusion

Although contrast enhanced spine imaging is commonly performed, there are significant gaps in the process of obtaining informed consent for the use of contrast material. There are substantial deficiencies in the process of providing information to patients, in the documentation of the process of obtaining informed consent, and in patient participation in the process. Addressing these problems will require development and implementation of standardized protocols as well as improved methods of communication with patients. Improved informed consent for contrast material will require a combination of the best practices of all of the stakeholders involved in providing imaging services to patients.

Improving the informed consent process requires a variety of approaches. These can include developing and implementing guidelines for informed consent for spinal imaging, utilizing structured forms or checklists for informed consent, and improving communication between health care providers and their patients.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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