Advance Consent for Interventional Radiology Procedures

Quality Improvement Project

Abstract

Background

Advance consent is crucial for patients undergoing Interventional radiology (IR) procedures with potential serious harm. Two previous audits at our hospital revealed issues with obtaining consent before the day of the procedure, leading to the implementation of a consent clinic. Subsequently, a new electronic patient record (EPR) system was introduced. This third audit cycle assessed whether these changes improved the advance consent rates for vascular IR procedures.

Method

We retrospectively reviewed 53 patients who underwent vascular IR procedures in January 2023, noting whether each procedure was inpatient or outpatient, urgent or elective, and the procedure type. These results were compared with previous cycles to evaluate adherence to consent standards.

Results

Among the 53 patients, there was an even split between inpatient and outpatient procedures, as well as between urgent and elective procedures. 27 patients underwent lower limb angiogram/angioplasty, 19 had fistula work, and 7 underwent other procedures. 77% of patients consented in advance or had the consent process initiated beforehand.

Conclusion

An improvement in advance consent rates was noted compared to previous cycles (14% → 63% → 77%) following the implementation of consent clinics and the new EPR system. However, 33% of patients, primarily those undergoing fistula work, still consented on the day of the procedure. This audit highlights the benefit of the new EPR system and the need to continue consent clinics, emphasizing the importance of advance consent, especially for fistula procedures.

Keywords

Interventional Radiology, Informed Consent, Audit, Electronic Records, Vascular

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Background

Informed consent and shared decision-making are important pillars of good medical practice.(1) Advance consent is the process by which patients provide informed agreement to medical or surgical procedures before the initiation of care, often during pre-procedural consultations. This approach is grounded in ethical principles of *autonomy*, *respect*, and *shared decision-making*, and evidence suggests it offers several benefits for both patients and healthcare providers.

Studies indicate that advance consent enhances patients' comprehension of procedures, risks, and alternatives. A systematic review by Schenker et al. (2) found that clear, upfront communication improves informed decision-making, allowing patients to weigh the risks and benefits effectively. Pre-procedural discussions and consent reduce patient anxiety by addressing concerns, providing clarity, and fostering trust. Study by highlighted that patients who had adequate time to discuss procedures reported lower levels of pre-operative stress and felt more empowered in their care decisions. (3) Feedback from patient surveys consistently shows higher satisfaction with care when advance consent is obtained. According to principles of patient-centred care developed by the Picker Institute, patients valued being given ample time to ask questions and felt more respected when healthcare professionals prioritised advance discussions. (4) Patients who are better informed and mentally prepared for procedures often have improved recovery outcomes. Studies indicate that advance consent contributes to better adherence to pre- and post-procedural instructions, reducing complications and recovery time. (5)

Patient feedback studies underscore the importance of tailored communication during advance consent. Patients prefer consent discussions that avoid excessive medical jargon. Surveys suggest that patients value visuals or decision aids to support understanding (6). Patients often feel rushed during consent processes, which diminishes satisfaction. Allowing time for reflection and follow-up questions improves their experience. Patients report greater trust and satisfaction when providers actively engage them in discussions, rather than treating consent as a formality. While advance consent is widely beneficial, challenges remain. Studies suggest that patients with limited health literacy or from marginalised communities may struggle to fully engage in the process without additional support. Tailored strategies, such as culturally appropriate communication and decision aids, are crucial to overcoming these barriers.

Interventional radiology (IR) departments can be very busy with high patient turnover within both vascular and non-vascular procedures. Our department carries out a large volume of procedures, for which consent usually is conducted on the day of the procedure. Preferred standards of practice for patients undergoing any significant procedure states the consenting process should be completed, or discussed in detail, before the day of a procedure. (7) This allows patients to understand and reflect on the information provided and clarify details further with their physician fostering a shared decision-making approach.(8) Improved knowledge and understanding of the key components of their treatment has been shown to influence patient satisfaction.(9)

The minimum elements of an informed consent form include the specific procedure, physician performing the

procedure, statement that the procedure was explained alongside a patient signature with the relevant date and time. (10) A cross-sectional study by Guzman et al explored the patient satisfaction results of 150 women undergoing elective gynaecologic surgery. (11) A post-operative survey was used to explore patient views post-operatively to determine if women felt they had decided in their best interests and were adequately informed of what they could expect. Click or tap here to enter text.The study demonstrated that overall, 71% of patients were highly satisfied with their decision having adequately consented pre-operation. A prospective audit by Sharma et al explored informed consent in orthopaedic surgery evaluating the level of information attained by 76 patients after giving their consent and their overall satisfaction.(10) This study demonstrated that formal training (on obtaining consent) can improve patient experience and the added benefit of aids to improve patient recall and understanding. There is evidence from research that 'outpatient consent clinics' provide opportunities to counsel and complete the relevant documentation for informed consent before the patient's admission. Failure of obtaining informed consent can be harmful to patients' outcomes as well as leading to dissatisfaction.(12) Dissatisfaction from procedures such as mesh implants for stress incontinence and pelvic organ prolapse, demonstrate the consequences of inadequate information. (13)

Aim

This audit aimed at exploring the standards of the consent process in our Radiology Department specifically focusing on vascular IR procedures. Furthermore, our hospital implemented new electronic patient records (EPR) systems since the previous cycle of this audit. As EPR has been shown to improve patient data organisation, we reviewed the impact of the new system in allowing staff to consent patients in advance of procedures.

Outcome:

We assessed whether there is an increase in the number of patients consented in advance of vascular interventional radiology procedures following implemented changes, and whether this has been maintained with the advent of the new EPR software.

Methods

Data was retrospectively collected for January 2023 using the new EPR computer system recently implemented in the hospital. Data was initially provided by the Audit department and reviewed by both authors to extract the data on consent for each patient included.

We determined if patients had been consented in advance by the following:

- Signed consent form on EPR patient media before the day of the procedure.
- Documentation of a discussion on informed consent in EPR patient letters.

Inclusion criteria: All vascular IR procedures taking place in the IR department within January 2023 were included in the audit.

Exclusion Criteria: Hybrid, emergency cases and line insertions were excluded from the audit.

Results

This was the third cycle of the audit with the first cycle being undertaken in 2020 and the second cycle in 2021. Cycle one (n=28) in 2020 found 14% of patients were consented in advance of procedures. Cycle two in 2021 (n=27) demonstrated a significant improvement in number of patients being consented in advance, to

63%. The distribution of patients who were classified as elective, urgent cases and the procedures performed are documented in Table 1 and 2.

In cycle 3 (n=53) the mean age was 67.2 ± 14.8 years, and there were 33 male and 20 female patients. There was an even split between inpatient and outpatient procedures, as well as between urgent and elective procedures.

27 patients underwent lower limb angiogram/angioplasty, 19 had fistula work, and 7 underwent other procedures (Table 2 and 3).

77% of patients (41/53) were consented in advance or had the consent process initiated beforehand in this cycle. [Figure 1] This demonstrated a further improvement from previous cycles.

We found that patients (11/12) consented on the day of procedure were related to fistula work.

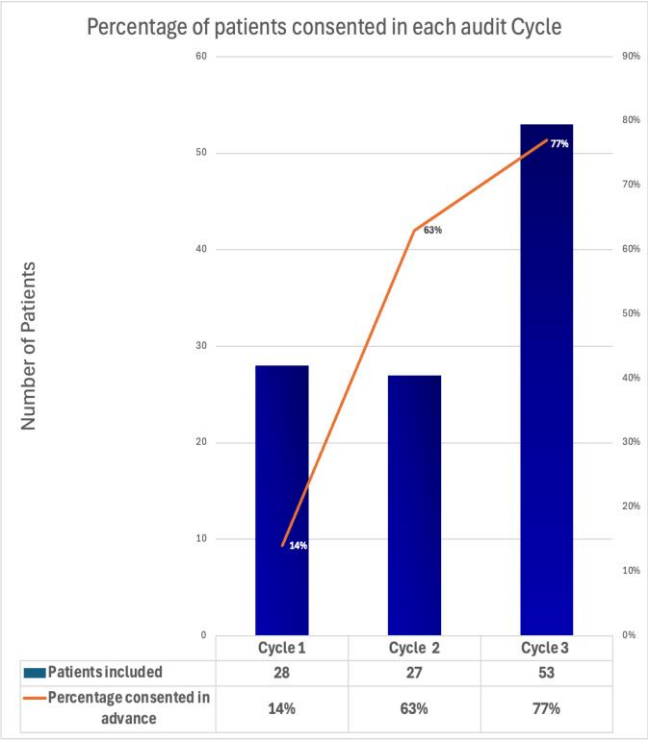

Figure 1 Cycle 1,2 and 3 Vascular IR consented in advance

	Cycle 1	Cycle 2	Cycle 3
	2020	2021	2023
Inpatients	6	14	25
Outpatients	22	13	28
Total	28	27	53

Table 1 Inpatient and Outpatient patient spread in Cycle one, two and three

	Cycle 1	Cycle 2	Cycle 3
	2020	2021	2023
Elective	18	11	25
Urgent	10	16	28

Table 2 Elective and urgent patients in Cycle one, two and three

	Cycle 1	Cycle 2	Cycle 3
	2020	2021	2023
Lower Limb Angiogram	14	12	27
Fistula	7	9	19
Other	7	6	7

Table 3 Procedures performed in Cycle one, two and three

Discussion

Following the first audit cycle in 2020, there was active departmental prioritisation on ensuring patients were consented prior to vascular IR procedures. Various changes have been implemented which resulted in an improvement.

- A consent clinic was set up for elective and outpatient procedures, and
- a vascular IR 'consultant of the day' model was initiated to deal with vascular radiology queries, and to take a lead on consenting inpatients in advance of their vascular IR procedures.
- Patients undergoing elective and outpatient procedures were provided a date in advance enabling them to have a discussion prior to the day of procedure with a consultant to understand what they can expect on the day. This enables patients to ask any further questions and familiarise themselves with the medical team.
- Patients were provided with written information sheets and online trust resources on their procedure supplementing the information provided to patients.

Implementation of the EPR system brought all patients into a centralised system and relieved the administrative burden allowing patients to be booked in advance of their procedure. The consultant of the day model ensured senior responsibility was provided. This reduced the likelihood of patients being missed for prior consenting of their procedure.

We determined that most patients not consented prior to the day of procedure were undergoing fistula procedures. Further emphasis on ensuring this cohort of patients is consented going forward will be key. We have recommended further stakeholder engagement to gain an understanding how these patients could be reached in advance in the future for prior consenting.

Conclusion

Advance consent is a valuable process that strengthens patient autonomy, improves satisfaction, and enhances procedural outcomes. Feedback from patients highlights the need for clear, patient-centered communication, adequate time for discussion, and tools to support understanding. These elements are essential to maximising the benefits of advance consent in clinical practice.

With increasing demand and number of Vascular IR procedures performed, the burden of achieving early consent and allowing adequate time and resources to assist patients in their understanding of the procedures will remain a challenge. Adoption of robust local standards, providing training to staff, and material resources made available on the intranet and in a format accessible to patients using videos, frequently asked questions via smart phones (QR codes) would help to provide informed consent. This is crucial to enable a allay anxiety and provide a better patient experience.

This audit highlighted ongoing improvements in consent through better use of EPR systems (14) in the latest cycle at our hospital, however further improvements are required to ensure all patients consented in advance of their procedures, particularly those undergoing fistula procedures. Future research or audits in the field may also benefit from exploring if there is any link between patients being consented in advance and the impact on patient outcomes post interventional radiology procedures.

We have been able to disseminate our findings locally to promote greater

discussion on the important topic of consent within IR. Systems implemented at our hospital to ensure responsibility and processes are put in place to improve consent have shown to be effective at improving departmental consent outcomes, meeting national guidelines.(15) Other centers can apply improvements we've made to our consent process such as implementing consent clinics, ensuring a senior clinician takes responsibility for consent and introducing a new EPR system to manage patient flow.

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Contribution statement

Both authors contributed to this article and were involved in leading the audit. They were both responsible for data collection, data analysis and write up of the results. Both authors contributed to the write up of this manuscript.

Conflict of Interest Statement

We have no conflicts of interests to declare.

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