

Putting NICE guidance into practice

**Clinical audit tool: Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis**

**Implementing the NICE guidance on ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis (IP****XXX)**

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Published: March 2015

This clinical audit tool accompanies the interventional procedure: [Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis](http://guidance.nice.org.uk/ipgXXX) Note - Add IP number to hyperlink when available

**Issue date**: 2015

This document is a support tool for clinical audit based on the NICE guidance. It is not NICE guidance.

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[Name of individual, job title, national organisation and/or trust.

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**Clinical audit tool**

NICE has recommended that ultrasound-enhanced, catheter directed thrombolysis for deep vein thrombosis should only be used with special arrangements for audit. This means that clinicians undertaking the procedure should audit and review the clinical outcomes of all patients. Audit data should be reviewed at appropriate intervals and practice should be changed if the results suggest the need to do so.

To help clinicians audit and review clinical outcomes NICE has produced this clinical audit tool, which is for use at local discretion. It contains clinical audit criteria and a data collection form which can be used in its current form or amended to suit local preferences.

A data collection form should be completed for each patient. Demographic information can be completed if this information is essential to the project.

Patient identifiable information should never be recorded on the data collection form and clinical audit data could be pseudonymised. For example, a secure file containing the audit IDs linked to the patient identifiable items of information could be held in a different location to the clinical audit data. This will enable the data to be linked to the patients again but it will mean that clinical audit data alone will not identify individuals.

To ensure that any valuable insight regarding the consequences of this procedure is shared among clinicians, serious or previously unrecognised patient safety incidents should be documented and information submitted to the National Reporting and Learning System (NRLS).

For further information about clinical audit, clinicians should refer to a clinical audit professional within their own organisation or the [HQIP website](http://hqip.org.uk/).

To ask a question about this clinical audit tool, or to provide feedback to help inform the development of future tools, email [auditsupport@nice.org.uk](mailto:auditsupport@nice.org.uk).

**Audit criteria**

|  |  |
| --- | --- |
| **Criterion 1** | The percentage of patients undergoing ultrasound-enhanced, catheter directed thrombolysis for deep vein thrombosis who have had any of the following clinical outcomes:   * thrombolysis success (grade II or III lysis) * clinical improvement (decrease in pain/swelling) * improved quality of life * long term patency * no recurrent thrombosis/stenosis * valvular reflux * post-thrombotic syndrome * other. |
| **Exceptions** | None |
| **Standard** | Outcomes from published literature should be considered when reviewing audit data, such as those set out in the [guidance](http://guidance.nice.org.uk/ipgXXX) Note add IP number to hyperlink when available. |
| **Data items** | See data collection tool, data items x to x |
| **Definitions** | Grade I: <50% thrombus removal, Grade II: 50% to 90% thrombus removal, Grade III: >90% thrombus removal.  Quality of life could be measured using the Short Form (36) Health Survey or Chronic Venous Insufficiency quality of life Questionnaire (CIVIQ).  Recurrence of thrombosis/stenosis could be measured using the Villalta scale.  The audit tool can also be used to collect data on overall infusion time and total drug dose to enable a comparison with catheter-directed thrombolysis alone.  Patients could be followed up at 1, 3, 6 and 12 months. |
| **Criterion 2** | The percentage of patients undergoing ultrasound-enhanced, catheter directed thrombolysis for deep vein thrombosis who have had any of the following adverse events:   * bleeding * pulmonary embolism * other. |
| **Exceptions** | None |
| **Standard** | Outcomes from published literature should be considered when reviewing audit data, such as those set out in the [guidance](http://guidance.nice.org.uk/ipgXXX) Note add IP number to hyperlink when available. |
| **Data items** | See data collection tool, data items x to x |

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| **Definitions** | **Adverse event grades** | |
| 0: | No adverse event |
| I: | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. |
| II: | Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and local parenteral nutrition are also included. |
| III: | Requiring surgical, endoscopic or radiological intervention |
| IIIa: | Intervention not under general anesthesia. |
| IIIb: | Intervention under general anesthesia |
| IV: | Life threatening complication (including CNS complications) requiring IC/ICU-management |
| IVa: | Single organ dysfunction (including dialysis) |
| IVb: | Multi organ dysfunction |
| V: | Death of a patient |
| Suffix ‘d’: | If the patient suffers from a complication at the same time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication. |
| For further definition of these grades please visit the [Surgical complication website](http://www.surgicalcomplication.info/index-2.html). | |
| **Criterion 3** | The percentage of patients undergoing ultrasound-enhanced, catheter directed thrombolysis for deep vein thrombosis who have:   * been told that there are uncertainties about the procedure’s safety and efficacy * received written information explaining that there are uncertainties about the procedure’s safety and efficacy * given written consent to treatment. | |
| **Exceptions** | If the patient is unable to understand information and/or give consent to treatment. | |
| **Standard** | 100% | |
| **Data items** | See data collection tool, data items x to x. | |
| **Definitions** | NICE recommends its [Information for the public](http://www.nice.org.uk/guidance/ipgxxx/informationforpublic). Note - Add IP number to hyperlink when available. This is written to help patients who have been offered this procedure (and their families or carers) to decide whether to agree to it or not. | |

**Data collection form**

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| **Audit ID:** | **Sex:** | **Age:** | **Ethnicity:** |

The audit ID should be an anonymous code. Patient identifiable information should never be recorded.

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| **Data item** | **Data** | **Tick/complete box as indicated** | | | |
| **Date of procedure and baseline data** | | | | | |
| 1 | Date of procedure | Date: | | | |
| 2 | Quality of life | Measure(s) used and score(s): | | | |
| 3 | Duration of thrombosis | Days: | | | |
| 4 | Extent of thrombosis | Extent: | | | |
| **Consent** | | | | | |
| 5 | Has the patient been told that there are uncertainties about the procedure’s safety and efficacy? | Yes |  | No |  |
| 6 | Has the patient received written information explaining that there are uncertainties about the procedure’s safety and efficacy? | Yes |  | No |  |
| 7 | Has the patient given written consent to treatment? | Yes |  | No |  |
| **Clinical outcomes – intraprocedural** | | | | | |
| 8 | Date of assessment | Date: | | | |
| 9 | Thrombolytic agent used | Name of drug: | | | |
| 10 | Dose of thrombolytic agent used | Dose: | | | |
| 11 | Overall infusion time | Hours: | | | |
| 12 | Thrombolysis success (grade II or II lysis) | Yes |  | No |  |
|  |  | Lysis grade: | | | |
| **Adverse events – intraprocedural** | | | | | |
| 13 | Bleeding | Grade: | | | |
| 14 | Other adverse event | Detail: | | | |
|  |  | Grade: | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Data item** | **Data** | **Tick/complete box as indicated** | | | |
| **Clinical outcomes – up to 30 days** | | | | | |
| 15 | Date of follow-up | Date: | | | |
| 16 | Clinical improvement (decrease in pain/swelling) | Yes |  | No |  |
|  |  | Detail: | | | |
| 17 | Improved quality of life | Yes |  | No |  |
|  |  | Score(s): | | | |
| 18 | No recurrent thrombosis/stenosis | Yes |  | No |  |
|  |  | Villalta score: | | | |
| 19 | Other clinical outcome | Detail: | | | |
| **Adverse events – up to 30 days** | | | | | |
| 20 | Bleeding | Grade: | | | |
| 21 | Pulmonary embolism | Grade: | | | |
| 22 | Other adverse event | Detail: | | | |
|  |  | Grade: | | | |
| **Clinical outcomes – all subsequent follow up (copy section as needed)** | | | | | |
| 23 | Date of follow-up | Date: | | | |
| 24 | Improved quality of life | Yes |  | No |  |
|  |  | Score(s): | | | |
| 25 | Patency | Yes |  | No |  |
|  |  | Detail: | | | |
| 26 | No recurrent thrombosis/stenosis | Yes |  | No |  |
|  |  | Detail: | | | |
| 27 | Valvular reflux | Yes |  | No |  |
|  |  | Detail: | | | |
| 28 | Post-thrombotic syndrome | Yes |  | No |  |
|  |  | Detail: | | | |
| 29 | Other clinical outcome | Detail: | | | |
| **Adverse events – all subsequent follow-up (copy section as needed)** | | | | | |
| 30 | Pulmonary embolism | Grade: | | | |
| 31 | Other adverse event | Detail: | | | |
|  |  | Grade: | | | |

**Adverse event grades**

0: No adverse event

I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.

II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and local parenteral nutrition are also included.

III: Requiring surgical, endoscopic or radiological intervention

IIIa: Intervention not under general anesthesia.

IIIb: Intervention under general anesthesia

IV: Life threatening complication (including CNS complications) requiring IC/ICU-management

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