

Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg258

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Intraoperative red blood cell salvage is an efficacious technique for blood replacement and its use is well established in other areas of surgery. The evidence on safety is adequate. The procedure may be used during radical prostatectomy or radical cystectomy provided normal arrangements are in place for clinical governance and audit.
- 1.2 Clinicians wishing to undertake intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy should ensure that patients understand the possible risks and benefits of the procedure compared with those of allogeneic blood transfusion, and provide them with clear, written information. In addition, use of the Institute's [information for patients](#) ('Understanding NICE guidance') is recommended.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 During either radical prostatectomy or radical cystectomy, patients may lose a considerable amount of blood. Conventionally, these patients receive a blood transfusion using allogeneic, banked blood, which carries a small risk of infection (for example, with hepatitis, human immunodeficiency virus [HIV], variant Creutzfeldt-Jakob disease [vCJD]) or antibody-mediated transfusion reaction). Exceptionally, autologous blood can be collected and stored before an elective operation, and transfused during or after the operation as required (see section 3.2).
- 2.1.2 Intraoperative red blood cell salvage offers an alternative to allogeneic or pre-donated autologous blood transfusion. It may also be useful in the treatment of patients who object to allogeneic blood transfusion on religious or other grounds.

2.2 Outline of the procedure

- 2.2.1 Blood lost during radical prostatectomy or radical cystectomy is aspirated from the surgical field using a suction catheter. The blood is then filtered to remove

debris. The filtered blood is washed or spun and the red blood cells are resuspended in saline, for transfusion during or after the operation. A leukocyte depletion filter is nearly always used; this is thought to minimise the risk of re-infusion of malignant cells that may be present in the aspirate. A number of different devices are available for this procedure.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

2.3 Efficacy

2.3.1 A case series of 49 patients treated with red blood cell salvage during radical cystectomy (either alone or in combination with other surgery) reported overall and disease-free survival rates of 88% (43/49) and 80% (39/49), respectively, at 24-month follow-up. No studies were available that described efficacy outcomes for the use of intraoperative red blood cell salvage during prostatectomy.

2.3.2 The Specialist Advisers considered key efficacy outcomes to include reductions in allogeneic transfusion requirements, haemoglobin levels and perioperative immunomodulation.

2.4 Safety

2.4.1 A non-randomised controlled study of patients who were treated with radical prostatectomy reported similar rates of biochemical prostate cancer recurrence in 265 patients treated intraoperatively with salvaged red blood cells and 773 patients who did not require re-infusion (15% and 18% respectively, $p = 0.76$) at 5-year follow-up. Subgroup analysis of patients at 'low', 'intermediate' and 'high' risk (Gleason score) also found no significant difference in biochemical recurrence rates between the two groups (absolute numbers not reported).

2.4.2 A second non-randomised controlled study of patients who were treated with radical prostatectomy reported biochemical recurrence in 5% (3/62) of patients treated intraoperatively with salvaged red blood cells at 7-month follow-up. The study reported biochemical recurrence in 24% (24/101) of patients transfused with pre-donated autologous blood at 43-month follow-up (substantially

different follow-up times noted). Progression-free survival was not significantly different between the groups ($p = 0.41$) at 43-month follow-up. In the same study, postoperative haematocrit levels were significantly higher in patients given salvaged red blood cells ($31.3 \pm 3.5\%$) than in those who received pre-donated autologous blood ($27.9 \pm 3.4\%$).

- 2.4.3 A third non-randomised controlled study of patients who were treated with radical prostatectomy reported that there was biochemical evidence of recurrence (based on blood levels of prostate specific antigen) in 19% (9/47) of patients treated intraoperatively with salvaged red blood cells at 43-month follow-up, and in 32% (17/53) of patients who did not require re-infusion at 46-month follow-up (statistical significance not stated). This study also reported that red blood cell salvage treatment was not an independent predictor of biochemical evidence of recurrence.
- 2.4.4 A fourth non-randomised controlled study of patients who were treated with cystectomy reported no significant difference in the 3-year overall survival rate between a group of 65 patients treated intraoperatively with salvaged re-infused blood and 313 patients who did not receive re-infusion (64% and 66% respectively; absolute numbers not reported; $p = 0.74$). Similarly, at 3-year follow-up, there was no significant difference in the disease-free survival rate between the groups (72% and 73% respectively; $p = 0.90$; absolute numbers not reported).
- 2.4.5 A case series of 49 patients who were treated with radical cystectomy and who received salvaged red blood cells reported that there were no complications directly related to red blood cell salvage transfusion at 24-month follow-up. No major reactions to transfusions were noted and no patient demonstrated clinical or biochemical evidence of hepatitis.
- 2.4.6 The Specialist Advisers considered key safety outcomes to include transient hypertension, length of hospital stay, need for intensive care unit stay, infection rates, thrombosis and bleeding. An additional theoretical adverse event noted by the Advisers was re-infusion of cancerous cells leading to distant metastases.

2.5 Other comments

- 2.5.1 The Committee noted concern about the theoretical risk of infusing viable

cancer cells that might cause metastases. However, there was no evidence in reported series that this occurred, and any such theoretical risk needs to be balanced against the potential risks of allogeneic blood transfusion. The Committee did not consider it likely that further long-term research would identify metastases that might have been caused by re-infused malignant cells.

3 Further information

- 3.1 The Institute has produced interventional procedures guidance on [intraoperative blood cell salvage in obstetrics](#).
- 3.2 NHS Blood and Transplant recommend use of the British Committee for Standards in Haematology's 'Guidelines for policies on alternatives to allogeneic blood transfusion' in relation to preoperative autologous blood transfusion.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

NICE considered the evidence relating to the [efficacy and safety of intraoperative blood cell salvage in obstetrics](#) (IPG144) and for intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy (IPG258) in response to concerns expressed about theoretical risks associated with the procedure. These concerns were the possibility of amniotic fluid embolism and haemolytic disease in future pregnancies when used in obstetrics, and reinfusion of malignant cells when used in radical prostatectomy/cystectomy.

The evidence relating to safety of cell salvage in these procedures was considered adequate and therefore NICE does not intend to review its use in other specific clinical situations unless notified

of new indications for intraoperative cell salvage in which there may be new safety concerns.

11 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Your responsibility

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).