SAFE ANAESTHESIA LIAISON GROUP

Guaranteeing Drug Delivery in Total Intravenous Anaesthesia

NHS
National Patient Safety Agency
National Reporting and Learning Service

SALG RECOMMENDATIONS

Current policy and practice for Total Intravenous Anaesthesia in both adults and children is reviewed to ensure that:

1. When administering TIVA a non-return valve is always used on any intravenous fluid line
2. Sites of intravenous infusions should be visible so they may be monitored for disconnection, leaks or infusions into subcutaneous tissues
3. When using equipment, it is essential that clinical staff know its uses and limitations
4. Organisations give preference to clearly labelled intravenous connectors and valves

Local practice should be audited and staff encouraged to report further incidents.

RATIONALE

Although this information refers to drug administration during TIVA, the same applies whenever any drug infusion is being given through the same cannula as an IV fluid infusion and serious complications may occur.

1 Using a one-way valve on the intravenous line

It is suggested that a one-way valve is used on IV fluid port when multi-lumen IV connectors are used.[1–2]

2 The site must be monitored throughout the procedure

Some reported incidents reflect poor vigilance of the cannula so disconnection of the infusion or displacement of the cannula was not noticed. In other incidents there was incorrect use of multi-lumen and other access equipment. Most medical pumps have alarms to detect pressure issues. Access to the cannula site may be difficult in operating theatre environments, but the general consensus of clinical advice (based on this evidence) is that cannula sites should be visually checked at regular intervals as a practical and simple risk reduction. In choosing the site for infusion, the anaesthetist should weigh up the balance of risks and benefit.

3 Using medical equipment

As the Agency responsible for making sure that medical devices are safe and fit for purpose, the Medicine and Healthcare products Regulatory Agency (MHRA) has prepared a booklet; 'Devices in practice – a guide for health and social care professionals' Aug 2008.[3] This provides a checklist process to ensure that any medical equipment (e.g. pumps and intravenous devices) being used are systematically checked and the user question their familiarity and competence with the equipment before use.

4 Organisations should ensure that all one-way valves purchased are clearly labelled

Clarity of information on packaging for single use items varies. There are a variety of multi-lumen/Y connectors in use for different situations.[3] Clear and informative packaging will aid correct selection of the appropriate system required for TIVA administration.

BACKGROUND

Unintended awareness during surgery may occur with all techniques of general anaesthesia. When TIVA is used to maintain anaesthesia, unintended interruption of the continuous infusion of anaesthetic agent(s) can lead to awareness if not detected promptly and corrected. Maintenance of anaesthesia during TIVA relies on continuous infusion of intravenous anaesthetic agents. Discontinuation of this infusion for any reason may cause the patient to experience a degree of awareness when consciousness was not intended. Anaesthetists often use multi-lumen or Y connectors to allow infusion of different anaesthetic agents with or without intravenous fluids to be given through a single intravenous cannula. A non-return valve prevents backflow of anaesthetic into the intravenous fluid line ensuring the patient is receiving the drug as intended. An anti-siphon valve offers protection against free-flow or siphonage in pump delivered medication lines.

One-way valve = anti-reflux valve, check valve, non-return valve

Further queries should be directed to: **salg@rcoa.ac.uk.**

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REPORTED EVIDENCE

A report received into the national Reporting and Learning System* (RLS) described an incident whereby TIVA was administered to a patient via a multi-lumen connecter. There was no one-way valve in the connector and as a consequence there was backflow of anaesthetic agent into the limb of the intravenous fluid line, rather than directly into the patient's vein. As a result of this, the reporting anaesthetist was concerned the patient may have experienced awareness during the anaesthetic.

Data from the RLS was searched from March 2008 to 15 June 2009. 89 incidents were found and all were reviewed. 49 were found to be relevant. Key issues identified were as follows:

- **Non-availability of appropriate pumps** – ten incidents; in two cases this was because the pumps had not been charged
- **Problems with pumps during TIVA** – 11 incidents; in one case the TIVA technique was abandoned; in eight cases the problems were noted immediately and the pump either changed or managed differently; in one case it was only noted at the end of the surgery that the pump had not delivered the appropriate amounts of agent.
- Two reports were of **syringes being 'switched'** with one relating to wrong labelling (Propofol and Remifentanil) and one where a 1% solution was used instead of 2%.
- Three cases were reported where **lines had been pulled out in error** and one where the cannula had 'tissued'.
- One case reported where **anaesthetist was not familiar with technique**.
- Three cases of **potential awareness** were reported but with no problems with TIVA being identified.
- 18 cases reported **problems with the intravenous line**:
  - Three related to Y connectors.
  - Three related to 3-way taps.
- Other incidents include, **kinking of lines, blocking of line, luer lock leaks and other leaks from lines, assumed fixed valves in lines becoming disconnected.**

In all of the above incidents reports:

- Five were reported where there was possible awareness intra-operatively; and
- Three situations described that had the potential for awareness.

The NPSA's Reporting and Learning System (RLS) was established to provide a national database of incidents relating to patient risks and harm. Interpretation of data from the RLS should be undertaken with caution. As with any voluntary reporting system, the data are subject to bias. Many incidents are not reported, and those which are reported may be incomplete having been reported immediately and before the patient outcome is known. It should also be recognised that there is significant under-reporting and therefore the data is likely to be an under-representation of actual incidents.

EXAMPLES OF INCIDENTS

'Infusion pump failed to deliver correct rate set. Pt anaesthetised using TIVA so when pt coughed they moved during anaesthesia, unsure why until rate delivered examined.'
'Patient, who was having Total Intravenous Anaesthesia (TIVA), was found to have a dislodged cannula at the end of the operation, meaning not all of the anaesthetic agent reached the patient. Patient aware.'
'Syringe empty and refilled. Infusion recommended but three-way tap left in 'refilling' position therefore infusion not delivered to patient for ten minutes, TIVA pump did not alarm .Patient moved during surgery. Awareness reported post-op.'
'Patient receiving TIVA anaesthetic. Pumps used for 45 minutes before it was noticed that syringes were switched in the TIVA pump so that the propofol infusion was infact remifentanil, and vice versa. Syringes had been filled and inserted into pump by (name). Patient data then added by (name) before connecting to patient and starting infusion.'
'Propofol TIVA cannula tissued (no occlusion warning from pump)patient had paralysis on board and was distressed at inability to communicate her state of awareness. Extra agents given once patient seen to move and increased BP.'

National Health Service Litigation Authority (NHSLA)
A search of the NHSLA database between January 2003 and March 2008 revealed 43 cases using the search criteria ['Anaesth' and ('aware' or 'awake' or 'woke up during' or 'awoke during' or 'total intravenous' or ' TIVA ')]. but on review, seven were not relevant and of the remaining 36, eight were related to obstetric anaesthesia for caesarean section, one to dentistry and the remainder to a range of surgical procedures. None specifically mentioned TIVA. A reading of the incident descriptions, however, could not exclude the possibility that TIVA may have been used in some of the cases.

Medicines and Healthcare products Regulatory Agency (MHRA)
MHRA section MDA/2007/089 states; 'where appropriate, consider using IV lines with one-way valves to prevent backtracking when more than one IV line is connected through a single access point. This can lead to under-infusion or bolus delivery of drugs.

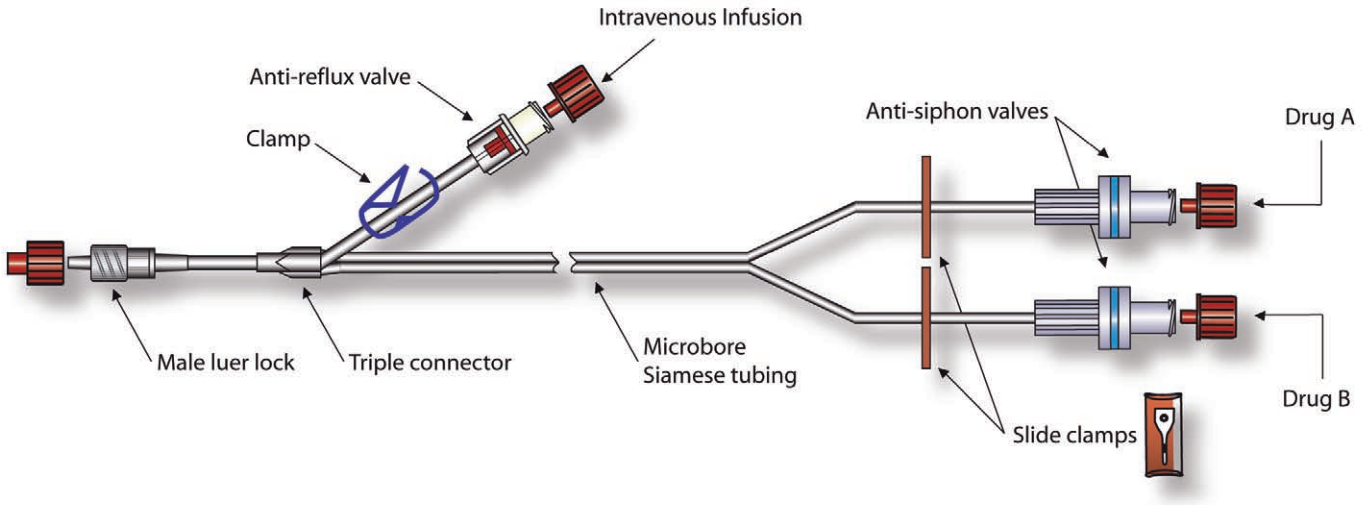
The literature on complications associated with TIVA
The search of existing literature has revealed a few case-reports highlighting some of the problems with the use of multi-lumen connectors, and other infusion devices4-6. Articles have been written regarding the safe use of infusion devices1. However, it has not been possible to identify any firm guidelines on how TIVA should be administered. Furthermore, no literature was found relating to the standardisation of the multi-lumen connectors.

Use of anti-siphon valves is recommended to reduce the risk of inadvertent free flow of drugs[1] – this can occur due to gravity if the syringe barrel or plunger is not engaged firmly in the pump mechanism. In addition, use of anti-reflux valves is recommended with multi-lumen connectors – the anti-reflux valve should be used at the port connected to intravenous fluids. Presence of the anti-reflux valve would prevent back flow of anaesthetic agents, which are driven by syringe pumps into the other ports, should a distal occlusion occur.[1]

Despite these recommendations, it is not uncommon to find multi-lumen connectors without any valves. Also, even if the valves are present, case reports highlight the problems associated with the failure of the valves[4] and leaks.[5–6]

CORRECT PLACEMENT DIAGRAM

This diagram shows a typical arrangement of a multi-lumen connector including an anti-reflux valve for IV fluid and anti-siphon valves for IV drugs.



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2 MDA/2007/089 – Intravenous (IV) infusion lines: all brands.
3 Devices in practice – a guide for health and social care professionals. August 2008.
4 Rutherford J. Failure of anti-reflux valve in a Vygon PCA set. *Anaesth* 2004;**59**: 511–512.
5 Yarham S, Woodall N. Leak of TIVA from Y-connector. *Anaesth* 2004;**59**:629.
6 Matthews AJ. A simple leak detection device for TIVA. *Anaesth* 2003;**58**:288.

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SALG has circulated this notice using
RCoA website, AAGBI website, NPSA Signals (pilot publication), RCoA Bulletin, AAGBI Anaesthesia News, e-mails to all clinical directors, college tutors and AAGBI linkmen.