Obstetric Anaesthetists’ Association Survey #168 (OAA-endorsed)

Non-Luer equipment for specialised procedures - epidural blood patch and spinal catheters

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In 2009 the NPSA started a process to change the connector used in neuraxial applications and regional anaesthesia to a non-Luer design. The equipment and processes for straightforward and high-volume procedures have been clarified, but the procedures in some niche areas remain unclear.

We wished to survey obstetric anaesthetists’ opinions about two specialised areas, the use of epidural blood patch to treat post-dural puncture headache, and continuous spinal anaesthesia using an indwelling spinal catheter.

METHODS

1640 members of the OAA were surveyed electronically in February 2016. There were 620 completed responses, giving a response rate of 37.8%.

RESULTS

Question 1. When the non-Luer neuraxial connector is used for epidural equipment, you won’t be able to do a blood patch using a Luer syringe - the Luer syringe containing venous blood will not attach to the non-Luer Tuohy needle. Please pick your preferred option to solve this problem.

- Take blood with Luer syringe and needle and then transfer the blood into a non-Luer syringe. 102
- Encourage companies to produce Luer Tuohys and LOR syringes just for blood patches. 62
- Use a specifically designed non-Luer blood taking kit, the syringe of which will then attach to the non-Luer Tuohy needle. 453
Question 2. Are you concerned with any risks from the preceding options?

Yes 442
No 178

**Syringe transfer**
- should not be done - no specific reason 36
- bacterial contamination 121
- sharp injury/ infection of staff 79
- clotting / haemolysis 66
- error / dural puncture 9

**Luer Tuohy**
- error / unfamiliarity 81

**Non-Luer Tuohy**
- error / misuse 39
- non-availability 41
- cost / not cost effective 31

Continued supply of Luer
- No development costs.

Concerns over specialised equipment:
- Introducing a special non-Luer blood-taking syringe and needle adds to possible confusion, as would having special Luer Tuohy needles that we could use for blood patches only.
- There is massive potential for a combination of kits to be used, with mismatched attachments.

Reassurance over non-Luer ‘kit’:
- If the non-luer blood taking kit is stored within the blood patch packaging and clearly labelled, then it should be safer than the other two options.
- Surety already produce a non-return needle system for taking blood into a Surety syringe. We have used this on several occasions without any problems.
- Currently use non-Leur blood patch kit - no concerns.

Lack of understanding of separate systems:
- Risk of identifying epidural space with Tuohy, then finding syringe doesn't fit, meaning need for second epidural attempt with different Tuohy and therefore increased risk to patient.
- Blood accidently being taken in the wrong syringe, and then finding out that they are incompatible.
Special circumstance:
- *None of these allow for the circumstance of a continuous epidural blood patch for a Jehovah’s Witness where the blood has to be in continuity.*

Error:
- *The non-Luer blood taking kit could be used to fill the syringe with other fluids.*
- *This entire process is useless, as I can still inject anything that I want down a special expensive needle.*

Uninformed:
- *This whole development is news to me.*

3. If a specific kit is required, would you see it as essential to be available before you change

| Yes   | 442 |
| No    | 178 |

Question 4. When neuraxial connectors for epidural and spinal injections change to non-Luer connectors, it is not currently anticipated that spinal catheters will be available at the same time. Do you feel these are essential products that would stop you changing to non-Luer connectors?

| Yes   | 97  |
| No    | 519 |

Question 5. Would you be happy to change, knowing that spinal catheters would follow in the next 6 months?

| Yes   | 534 |
| No    | 83  |

Question 6. Are you currently using non-Luer equipment for spinal anaesthesia?

| Yes   | 270 |
| No    | 338 |
Question 7. Are you currently using non-Luer equipment for epidural anaesthesia or analgesia?

Yes  82
No   534

Question 8. General comments:

70 responses

- Many comments that any change to non-Luer neuraxial equipment is unnecessary, costly or unsafe.
- I don't believe non-Leur lock equipment will improve patient safety and reduce harm, unless all drugs that are to be given are going to be supplied in pre-prepared syringes. As it stands, I can draw up any drug in any syringe that I wish, and so this new precaution will not prevent the inadvertent injection of drugs into the epidural or intrathecal space.
- Comments on the difficulty of the previous attempted introduction of non-Luer equipment, which lacked one single standard connector.
- Comments on the risk area being bag/spike, or epidural catheter connector, rather than Tuohy needle connector.
- Requirement to have non-Luer spinal equipment at same time as change of epidural equipment.
- Will all the manufacturers be ready for the change at the same time? The danger is that Luer + non-Luer will get mixed up (as has happened previously). What about the proximal end of the system?
- Another issue at the moment is the availability of longer needles in non-Luer manufacture.
- Has been a safety alert for many months, and as on Trust risk register we've changed despite an incomplete coverage of all potential requirements for accessing the neuraxis.
- Even the infiltration needles and syringes will need to be non-Luer to make this system "foolproof".
- Management of accidental dural taps at the time of epidural with intrathecal catheters should be possible with the change to the new system (ideally simultaneously).
- Some comments on existing non-Luer equipment being technically inferior to Luer; others say non-Luer equipment is satisfactory.
- We have not had any real problems with the switch over, the Surety blood patch kit is quite easy to use. We have the Vygon epidural system and it is just as good as any Portex system. We use Vygon and TeMeNa spinal needles which are excellent.
COMMENTARY

This survey was intended to gauge anaesthetists’ perceptions about the problems related to two specialised procedures that will be affected by the change to the ISO 80369-6 non-Luer connector for neuraxial devices in 2017 in the UK. We anticipated receiving responses from those both aware, and concerned, about these aspects. The response rate was therefore higher than expected, although we accept that the answers will not be representative of the membership as a whole.

The aim of the change to -6 is to ensure that drugs intended for intravenous use cannot be given neuraxially, and vice versa. The epidural blood patch procedure is a unique situation, comprising intentional transfer of an intravenous sample into the neuraxis. Syringe transfer maintains the two incompatible systems; the alternative is to use an i.v.-compatible system, or a neuraxial-compatible system, and restrict the availability and use of the products.

There was a clear majority in favour of using a non-Luer kit, thus maintaining consistency of neuraxial devices between applications. Syringe transfer is seen as carrying clinical risks both for the patient as well as staff. On the other hand, use of a Luer or non-Luer system are both seen as being clinically acceptable, but requiring care in ensuring appropriate availability as well as restriction of use only to the intended application. A Surety non-Luer version of this product is already in clinical use in some hospitals, with no reported problems.

One respondent was concerned that the change to non-Luer epidurals would prevent an epidural blood patch procedure with continuous circulation. However, we have sought clarification from the National Offices of the Jehovah’s Witnesses. Their view was that this procedural amendment is not currently used in standard practise anyway, but that it would be the right of the individual patient to choose or refuse the procedure carried out in the standard fashion. One of us (PS) has clarified that a particular supplier would be prepared to make a blood patch kit suitable for use with continuous circulation, with the manufacture of three simple add-ons, but they would need an indication that it was required in sufficient frequency to make it financially viable to produce such a product.

Continuous spinal anaesthesia is a technique that is currently not widespread, and is not listed as ‘core equipment’ by NHS England required to be available at the changeover. The vast majority of anaesthetists seem to be accepting of this situation. This does not mean that the technique cannot be used after the implementation date, but will have to be placed on the Clinical Risk Register (along with, for example, neurosurgical equipment).

A number of respondents made general comments indicating that they were not in favour of the change to non-Luer equipment. However, whatever the personal or departmental views about its desirability, the change will happen because of the liability that Trusts will incur if they do not comply. The introduction process will need careful management, and guidance is available from units that have succeeded already (see https://www.oaa-anaes.ac.uk/ui/content/content.aspx?ID=3475). Data from these units
indicate that clinical outcomes are unaffected and implementation was largely cost-neutral. The standardisation to one non-Luer neuraxial connector will ensure that choices between different suppliers’ products can be made freely, as is the case currently; it seems likely that suppliers will change the connector only, rather than other specifications of their devices.

The introduction of the non-Luer neuraxial connector will not prevent all types of error. Respondents also noted that there is still the potential for mistakes related to drawing up the wrong drug into a syringe intended for another route, as well as connecting drug bags using an i.v. giving set with spike. Solutions to these problems such as pre-filled syringes, bar coding and changing the bag-spike connector, must be encouraged as separate paths towards reducing medical errors. However, the non-Luer neuraxial connector will fill one large hole in the cheese.

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