Original Article

Description of a new non-injectable connector to reduce the complications of arterial blood sampling*

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Summary

Arterial cannulation is associated with complications including bacterial contamination, accidental intra-arterial injection and blood spillage. We performed a series of audits and experiments to gauge the potential for these, as well as assess the possible contribution of a new device, the Needle-Free Arterial Non-Injectable Connector (NIC), in reducing these risks. The NIC comprises a needle-free connector that prevents blood spillage and a one-way valve allowing aspiration only; once screwed onto the side port of a three-way tap, the device can only be removed with difficulty. We performed a clinical audit of arterial monitoring systems in our intensive care unit, which showed an incidence of bacterial colonisation of five in 86 (6%) three-way tap ports. We constructed a manikin simulation experiment of the management of acute bradycardia, in which trainee doctors were required to inject atropine intravenously. Ten of 15 (66%) doctors injected the drug into the three-way tap of the arterial monitoring system rather than into the intravenous cannula or the central venous catheter. In a laboratory study, we replicated the arterial blood sampling and flushing sequence from a three-way tap, with the syringes attached either directly to the three-way tap port or to a NIC attached to the port. The first (discard) syringe attached to the three-way tap was contaminated with bacteria. Bacterial growth was found in 17 of 20 (85%) downstream flushed samples (corresponding to the patient's circulation) when the three-way tap was accessed directly, compared to none of 20 accessed via the NIC ($p < 0.0001$). Growth was found on all of 20 (100%) ports accessed directly compared to none of 20 accessed via the NIC ($p < 0.0001$). The NIC effectively prevents bacteria from contaminating sampling lines. As its design also prevents accidental intra-arterial injection, we suggest that it can reduce complications of arterial monitoring.

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Introduction

Arterial cannulation is commonly used to improve the care of surgical and critical care patients. However, the cannula, transducer and sampling systems are associated with infective and thrombotic complications [1]. Accidental intra-arterial injection of drugs intended for intravenous delivery may also occur, resulting in serious sequelae such as loss of a limb or even death [1, 2]. The standard arterial transducer system provides no impediment to intra-arterial injection. Blood spillage, exsanguination and bacterial contamination are other potential complications when using the standard three-way tap [3]. It is not commonly appreciated that arterial cannulae are prone to colonisation and infection at a similar rate to central venous catheters [4]. No real solutions have been proposed to these problems. In this article, we present a clinical audit of bacterial contamination of arterial line three-way taps, a simulation study of accidental intra-arterial injection and a laboratory study of bacterial transfer through the arterial sampling system using either the standard three-way tap or a new purpose-built device; the Needle-Free Arterial Non-Injectable Connector (NIC; Amdel Medical, Liverpool, UK). This device has a one-way valve to allow blood sampling while reducing or abolishing the risk of bacteria entering the patient's circulation and accidental arterial injection, and a stop valve to prevent accidental blood spillage when sampling. The aims of this series of studies were to determine the incidence of arterial sampling port colonisation in an intensive care unit (ICU), the likelihood of accidental arterial injection for time-pressured junior doctors in an emergency simulation model, and the protection offered by the NIC against transmission of bacteria.

Methods

The audit was registered with the Queen Elizabeth Hospital Audit Department and the Research and Development Committee agreed that Regional Ethical Committee authorisation was not required. Bacterial contamination of the female side port of three-way taps in the arterial transducer system was assessed from November 2012 until July 2013. Patients included in the audit had an arterial cannula inserted in either the operating theatres or the ICU. Standard practice for insertion of an arterial cannula was to clean the insertion site with a 2% chlorhexidine-containing sponge stick (Chloraprep; Carefusion, Basingstoke, UK) and to use sterile gloves and a small drape contained in a dressing pack, as suggested in guidelines from the Association of Anaesthetists of Great Britain and Ireland [5]. The complete arterial monitoring system was changed every 72 h as per local and national guidance [6]. A representative convenience sample of side ports were cleaned with Sani-Cloth 2% chlorhexidine in 70% isopropyl alcohol wipes (Sani-Cloth, PDI, Flint, UK) and swabbed on day 3 before replacement with a new set, and immediately delivered to the microbiology department for culture. We set an audit standard of zero for colonisation of arterial ports with bacteria.

For the simulation study, we created a clinical scenario in an ICU environment using a Laerdal SimMan® simulator (Laerdal Medical Limited, Kent, UK). As a training exercise, trainee doctors who worked in areas where they might be required to respond to an emergency situation were recruited. Written consent was obtained from participants to participate and to use the anonymised results for publication. They were asked to manage a postoperative patient complaining of chest discomfort with severe bradycardia and associated hypotension. Monitors displayed heart rate, ECG, oxygen saturation, and invasive and non-invasive blood pressure. The manikin had a green 18-G intravenous cannula (Vasofix Safety; B Braun, Melsungen, Germany) in the right antecubital fossa, a four-lumen central venous catheter (Arrow-Howes Quad-Lumen; Teleflex Inc, Athlone, Ireland) in the right internal jugular vein and a red 20-G arterial cannula (BD Arterial Cannula; Becton Dickinson, Sandy, UT, USA) in the left brachial artery. The arterial cannula was connected to a transducer/flush system with a red three-way tap and red bung (Monitoring set single; CODAN pvb Medical GmbH, Lensahn, Germany). The intravenous cannula was covered by the bedding sheet and so was not immediately visible. Atropine or adrenaline in a pre-filled labelled syringe was available on request and the participants were asked to administer the drug themselves.

The laboratory study compared the transmission of bacteria when sampling from the side port of

a three-way tap or when sampling from a three-way tap with the NIC attached. The NIC has been developed at The Queen Elizabeth Hospital NHS Trust (Kings Lynn, UK) in partnership with the NHS Innovation Alliance (Health Enterprise East, Papworth, UK) and produced by Amdel Medical, Liverpool, UK (Fig. 1). It consists of a sampling port containing a one-way valve allowing outward flow and a needle-free valve that opens when a Luer syringe tip is inserted. There is an adjustment to the thread of the distal male Luer-lock end on the NIC that allows it to be screwed easily onto a female Luer connector, but with an impediment to removal. Blood samples can be taken from the NIC in the standard fashion. The device is then flushed by attaching a discard syringe to the port and activating the flush device of the transducer system for a volume of approximately 3 ml.

A system was prepared under sterile conditions to mimic the components and process of taking blood samples from an arterial monitoring system. This consisted of a 10-ml 'flush' syringe in place of the proximal transducer system connected with a 30-cm length of tubing (1-ml dead space) to a three-way tap; this was then connected with 30-cm tubing to a second 10-ml 'patient' syringe substituting for the distal tubing, arterial cannula and patient circulation (Fig. 2). The system was primed with saline solution, and the flush and patient syringes were filled to 10 ml. Samples were taken from the side port of the three-way tap directly or from a NIC attached to the side port.

The sampling sequence was performed as follows:

1 The tip of a 5-ml discard syringe was dipped into a broth containing mixed pathogens at a concentration of 10^7 cfu.ml^{-1}, following which it was attached to the three-way tap. Three millilitres was aspirated from the patient syringe into the discard syringe.
2 The discard syringe was substituted for a 5-ml sample syringe, and 3 ml was aspirated from the patient syringe into the sample syringe.
3 A 5-ml waste syringe was attached to the three-way tap, and 3 ml was injected from the flush syringe into this.
4 Three millilitres was injected from the flush syringe into the patient syringe.

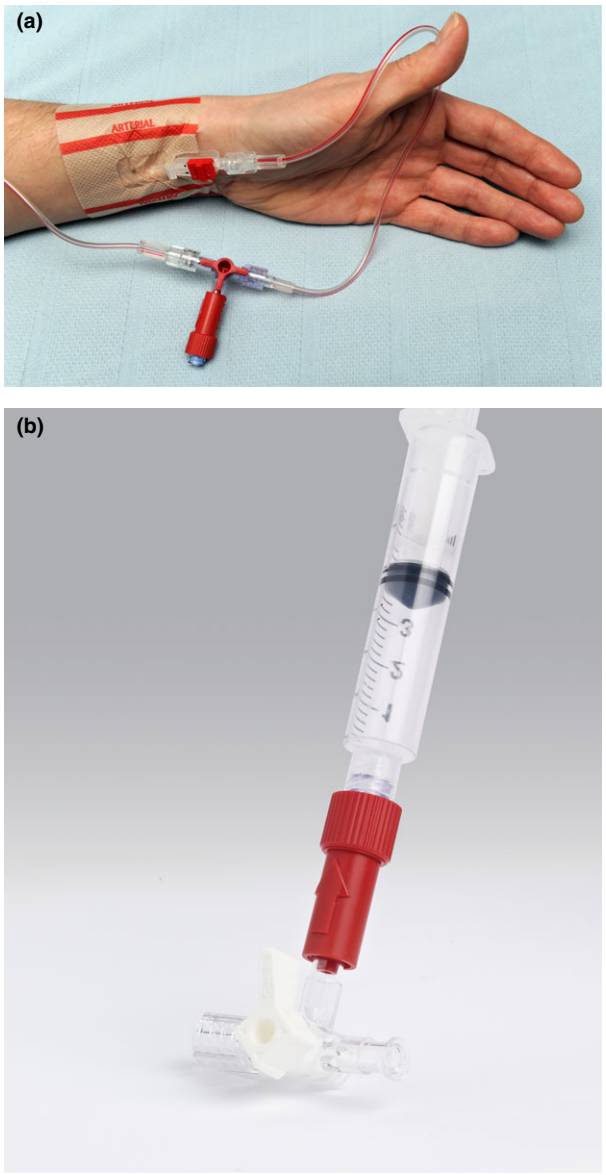

Figure 1 The Needle-Free Arterial Non-Injectable Connector (a) connected to a three-way tap (b) with a Luer-lock syringe connected to the sampling port of the device.

During this process, the three-way tap was turned to allow directed flow, as during clinical blood sampling.

The patient syringe was then disconnected from the system and 3 ml was injected into a sterile container. A sterile swab was inserted into the container and immediately inoculated on to Columbia Agar (horse blood) plates and incubated at 35 °C for 48 h. In both groups, the port of the three-way tap was also

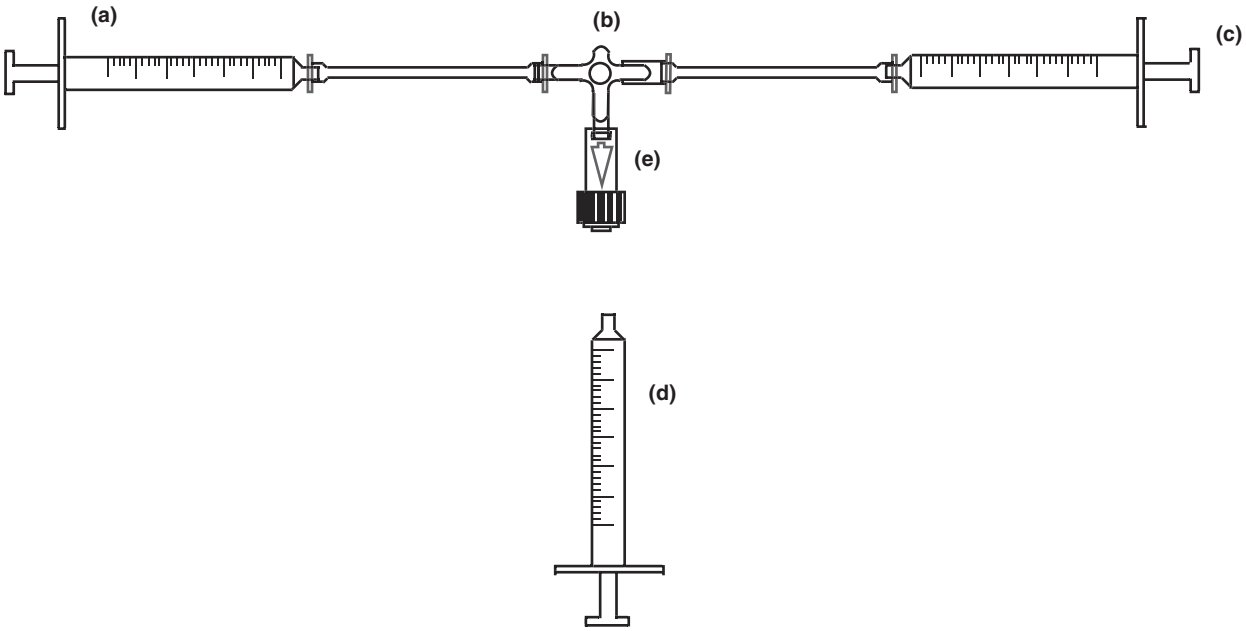

Figure 2 Schematic diagram of the system used to assess bacterial contamination during sampling with a three-way tap or the Needle-Free Arterial Non-Injectable Connector (NIC). a – flush syringe; b – three-way tap; c – 'patient' syringe; d – syringe (discard/sample/waste) connected either directly to side port of three-way tap, or to e – NIC. See text for details.

swabbed; in the NIC group, this was after the NIC was forcibly removed from the port using arterial forceps.

The experiment was repeated 20 times for each group. Colonisation rates were compared with two-tailed Fisher's exact test using GraphPad (GraphPad Software Inc., La Jolla, CA, USA).

Results

All of the arterial transducer systems used for the clinical audit of bacterial contamination had been in place for less than 72 h. Five of 86 (6%) three-way tap ports were contaminated with bacteria.

For the simulation study, 15 doctors were recruited. Their seniority was: eight Foundation-Year Trainees, four Core Trainees, one Speciality Registrar and two Trust Doctors. In the clinical simulation, all participants recognised a severe bradycardia and advocated atropine for treatment. Ten (67%) participants administered the atropine using the three-way tap in the arterial system, four (27%) used the intravenous cannula and one (7%) used the central venous catheter.

The laboratory study of contamination showed bacterial growth in 17 (85%) of the flushed samples using the three-way tap compared with none of the samples using the NIC ($p < 0.0001$). Twenty (100%) of the swabs taken from the directly accessed three-way tap ports were contaminated, and none from the ports used with the NIC ($p < 0.0001$).

Discussion

Complications of intra-arterial injection range from transient pain on injection to serious sloughing of skin and gangrene of the affected limb. Major complications occur in < 1% of cases, therefore arterial lines are deemed to be a safe procedure [4]. However, there are many cases reported of accidental injection into arterial lines with significant complications, with patients developing necrosis and requiring debridement of ischaemic areas [1–3].

We found a 6% contamination rate of three-way tap side ports in the arterial monitoring system in spite of following best practice guidelines [5, 6], consistent with the findings of Lucet et al. [4]. All the side ports were sampled in the ICU. The majority of them were sited and used in the operating theatre and subsequently the patient was transferred to the ICU;

therefore contamination could have occurred in either location.

The simulation study indicated a worrying frequency of mistakes. Arterial monitoring systems use one or two three-way taps to allow sampling of arterial blood. These are distinguished from venous access lines using red colour coding, labelling and thick non-compliant tubing that is sometimes also colour-coded. However, there is no impediment to arterial injection. The scenario was designed to be stressful and the intravenous cannula, the access route of preference, was deliberately hidden from view. It is of concern that 66% of the participants injected atropine via the arterial system, and in all cases, this error was unrecognised by the doctor concerned; it is possible therefore that accidental wrong route arterial injection is under-reported unless witnessed by an observer. We acknowledge that the actual rate of arterial wrong route injection in clinical practice is likely to be much lower than this, but it demonstrates the importance of creating systems that make such an error impossible.

The laboratory study clearly shows the potential for transmission of bacteria to the patient during a standard arterial blood sampling procedure, despite no direct injection's being made into the three-way tap. The presence of the one-way valve in the NIC prevents fluid ingress and therefore also prevents contamination of the system. Although, in this case, we used a heavily contaminated discard syringe at the start of the simulated blood sampling procedure, colonisation of intravascular systems is recognised both for arterial as well as venous applications in clinical practice [4].

Our study demonstrates that the NIC prevents transmission of bacteria to the patient circulation. It also prevents accidental injection, and because the valve has to be accessed using a syringe, it eliminates accidental blood spillage from the three-way tap. The NIC is designed to attach firmly to a three-way tap; it is possible to unscrew it manually with difficulty or by using arterial forceps, so is unlikely to be removed accidentally. Currently, an implementation study across the East of England is being undertaken under the auspices of the Eastern Academic Health Science Network (EAHSN) to determine efficacy, utility and user preferences for the NIC including assessing the optimal degree of difficulty for removal of the device; depending upon the feedback from users, this aspect will be fine-tuned in the manufacturing process.

The NIC received regulatory approval in Europe in October 2013; we suggest that this device provides significantly greater safety for patients managed with intra-arterial systems.

Competing interests

Funding received from the Queen Elizabeth Hospital, Kings Lynn, Critical Care Foundation.

The Queen Elizabeth Hospital owns a patent for the Needle-free arterial non-injectable connector and Drs Carter and Young have a profit share arrangement.

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