National Patient Safety Agency

National Reporting and Learning Service

Rapid Response Report NPSA/2009/RRR007:
Reducing risks of tourniquets left on after finger and toe surgery

December 2009

Supporting Information

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Introduction

The National Patient Safety Agency (NPSA) has issued a Rapid Response Report (RRR): 'Reducing risks of tourniquets left on after finger and toe surgery' [NPSA/2009/RRR007].

It is anticipated that the RRR, supporting information and clinical briefing sheet are for all healthcare settings where finger and toe surgery is undertaken or where the treatment of minor injuries to digits is carried out.

Background

Tourniquets are used in hand and foot surgery because of the need for a bloodless field during the procedure[1]. They may also be used in emergency departments, GP surgeries and other community settings (for example podiatry clinics) for minor surgical procedures or to treat minor injuries to digits. A rubber band is wrapped around the base of the digit forming a tight band.

As part of a wider assessment of problems in tourniquet management, a particular issue about the use of gloves as tourniquets was identified and evidence from the wider database reviewed by the NPSA in July 2009. This highlighted the number of incidents relating to harm caused by tourniquets (rubber and glove) used for hand and foot surgery left *in situ* post-operatively.

Specialist advice was sought from the Royal College of Surgeons and others, and some key aspects of safer practice were identified.

Scale of the patient safety issue

Data from the Reporting and Learning System (RLS)

A search of the RLS data from inception (November 2003) to 23 November 2009 was carried out to identify similar incidents relating to the trigger incident. A total of 149 cases were reviewed and 15 relevant incidents were identified, dating between the 23 August 2005 and the 23 November 2009, with the following degrees of harm:

Classification of harm	**Numbers**
Amputation required	2
Further treatment required	8
Not known	5
Total	**15**

Type of tourniquet used	**Numbers**
Surgical glove	6
Not known	9
Total	**15**

Where the incident occurred	Numbers
Operating theatres	9
Emergency departments	4
Community	2
Total	**15**

Although the numbers of patients affected are relatively small, the degree of harm that requires amputation of the affected digit or further surgical treatment is great.

Examples of incidents include (direct quotes from the RLS database):

'Patient had termination of tip of right ring finger. He attended plastic dressing clinic for routine follow up. When the dressing was removed his ring finger was necrotic and still had what looked like glove tourniquet in situ. Explained to patient he will require amputation (severe harm).'

'Finger tourniquet left in situ for 14 days following minor surgery of wound debridement pulp left middle finger. Patient required amputation of finger. Initial operation performed on [day one], tourniquet discovered on [day 13] and amputation of the left middle finger carried out on [day 14] (severe harm).'

'Whilst changing dressing to feet S/N noticed? band around 2nd toe L foot. (Pt had surgery 5/7 ago to remove toenails). Consultant clinic (no harm).'

Note: Staff are reminded that all issues relating to medical devices, including CE marked tourniquets, should be reported to the Medicines and Healthcare Products Regulatory Authority (MHRA).

National Health Service Litigation Authority (NHSLA) data

The NHS Litigation Authority (NHSLA) has had 14 relevant claims for the period 1 January 2004 to 23 November 2009, with the highest payment to date exceeding £100,000.

There are 14 relevant cases in the NHSLA Database for the period 1 January 2004 to 23 November 2009, all of which resulted in financial settlements.

Examples of incidents include (direct quotes from the NHSLA):

'Patient admitted for bilateral toe surgery. Tourniquet left on right toe. Re-admitted to hospital two days later complaining of no sensation in right toe. Tourniquet removed and toe black. Further surgery required.'

'Failure to remove tourniquet resulting in amputation of right big toe.'

'Failure to remove tourniquet following removal of cyst from little finger right hand. Patient returned to minor casualty - tourniquet found and removed - patient referred to hand surgeons.'

Literature review

The literature on complications associated with the use of finger and toe tourniquets

A search of the published literature* found very few relevant publications. There were case studies reporting harm from tourniquets left on in error following a procedure. Two examples are:

- De Boer and Houpt[2] reported that when treating a tip avulsion in a five-year-old boy the tourniquet (a rubber glove) was accidentally left in place. This resulted in a necrotic finger that had to be amputated. The authors discuss how "painless" ischemia can occur because after the operation, the finger is still numb from the local anaesthesia and nerves are the first structures in the digit to become damaged by the pressure of the tourniquet.

- Haas[3] reported a necrosis of the big toe in a 20-year-old woman with an ingrowing toenail after a tourniquet that was left in place after the operation. The ischemia, which lasted for two days, resulted in subtotal necrosis of the big toe.

The number of case studies reported is not an indication of the incidence of tourniquets left on digits.

In addition to case studies, three publications from the 1980s reported studies measuring the pressure of the different commonly used digital tourniquets.

Potential risk reduction strategies

A paper from the Pennsylvania Patient Safety Authority in 2005[4] describes 125 reports from health facilities of tourniquets being left on extremities in the previous year. While these reports do not include incidents of tourniquets left on digits (mainly relating to tourniquets left on after phlebotomy or intravenous access), some of the findings appear relevant to the current discussion. These include problems of visibility with tan-coloured tourniquets and the vulnerability of certain patients (younger and older) who may not be able to recognise or communicate problems to staff.

In the absence of other evidence, some pragmatic approaches have been suggested with the aim of reducing risks. For instance, Smith et al describe a method for digital tourniquet using a rubber glove technique with artery clip[5].

Overall, there is little high quality evidence to support any risk reduction strategies, including the use of gloves as tourniquets with modifications, and further research is needed. In the meantime, some actions to make practice safer have been suggested by clinical experts and shared with the Clinical Safety Board and a number of stakeholders when consulting on this draft guidance.

Medline, CINAHL and Embase using search terms: tourniquet AND (digit OR toe OR finger) AND (injury OR damage OR amputat* OR ischemia OR ischaemia OR necrosis OR necrotic).

- Controlling/reconciling the number of tourniquets used via checklists (WHO Surgical Safety Checklist)[6]. Guidance regarding recommendations for swab, needle and instrument counting are available to inform local policy. The Association for Perioperative Practice (AfPP), *Swab, Needle and Instrument Counts: Managing the Risk*[7] states: 'When additional items are added to the field, they should be counted when added and recorded as part of the count documentation'. It is recognised that some clinical areas, e.g. primary care and emergency departments, may not conduct formal swab and instrument counts. Therefore, a robust system for the verification of the tourniquet at the end of the procedure is vital.
- Using purposely designed tourniquets – clear advice from the regulatory body (MHRA) states that staff should only use devices for their intended purpose[8].
- Using tourniquets with high visibility design features, including labels and colour[4].
- Informing patient and/or family regarding the use of digital tourniquets[4].

Summary and conclusion

A review of national incident data showed a small number of cases where patients had suffered significant harm, including amputation from tourniquets left on after finger or toe surgery. Litigation data suggests at least 14 other cases where payments were made following harm to patients.

There is little high quality evidence in this area, but some key aspects of safer practice have been identified by clinical experts and regulatory advice[8]. These were confirmed at a small meeting of experts convened by the Clinical Board for Surgical Safety in November 2009.

Key actions outlined in the RRR are:

- Guidelines include the removal of digital tourniquets as part of the swab counting procedure and the need to record the length of time a tourniquet is in place.
- CE marked digital tourniquets which are labelled and/or brightly coloured should be used, in accordance with manufacturers' instructions. Surgical gloves should not be used as tourniquets.
- The WHO Surgical Safety Checklist is reviewed locally to consider adding tourniquet removal at 'Sign Out' stage.
- The NPSA briefing sheet is used to raise awareness of risks using digital tourniquets and safer practice recommendations (www.nrls.npsa.nhs.uk/tourniquets)

There is no definitive evidence on the relative safety of tourniquets and other devices (such as gloves) used as tourniquets. However, purpose designed visible tourniquets are available and are intended for this use. Data from reported incidents suggest that at least some of the preventable harm is caused by the use of surgical gloves. While the cost of CE marked tourniquets is higher* than a pair of sterile surgical gloves, the cost of

* At the time of print, a typical cost comparison (list price) per unit is: Surgical gloves (pair) - £1.09; CE marked tourniquet - £1.57 - £2.43

litigation claims can run to five or six figures. All of the incidents cited in this report were preventable and could have been avoided by implementing the four key actions in this guidance.

Appendix 1: Suggested compliance checklist

The table below gives suggested evidence that organisations may wish to use locally as assurance of compliance with this RRR.

Action	Summary of rationale	Compliance checklist
1. Guidelines include the removal of tourniquets as part of the swab counting procedure and specify the need to record the length of time a tourniquet is in place.	To ensure that digital tourniquets are not left in place for longer than recommended and the removal of the tourniquet is verified at the end of the procedure.	A record of the review of locally agreed guidelines to ensure a robust system is in place.
2. CE marked digital tourniquets which are labelled and/or brightly coloured should be used, in accordance with manufacturers' instructions.	Surgical gloves are not intended for this purpose (MHRA)[8].	A record of purchasing decisions made and the agreed tourniquets of choice.
3. The WHO Surgical Safety Checklist is reviewed locally to consider adding tourniquet removal at 'sign out' stage.	To ensure a robust risk reduction system for use of tourniquets.	A record of the review of the Surgical Safety Checklist and subsequent decisions made.
4. The NPSA briefing sheet is used to raise awareness of risks using digital tourniquets and safer practice recommendations (www.nrls.npsa.nhs.uk/tourniquets).	This provides a simple and quick risk reduction measure to raise staff awareness whilst local work on the other action points is taken forward.	Information could be posted on local intranets, included in staff induction packs and teaching aterials, or adapted for use in local staff newsletters and bulletins.

References

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