A service evaluation of the iTClamp™50 in pre-hospital external haemorrhage control

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Abstract
It has long been accepted that uncontrolled haemorrhage is a leading cause of early death in trauma patients, with the majority of deaths occurring in the pre-hospital setting. While most cases of haemorrhage can be dealt with using standard dressings, tourniquets and haemostatic agents, some anatomical areas such as the head, neck, axilla and junctional areas continue to be problematic, as it is challenging to apply tourniquets or trauma pressure dressings to these areas effectively.

One device designed to overcome this issue is the iTClamp™50, which was the subject of a service evaluation by the North East Ambulance Service NHS Foundation Trust, from July 2014 to February 2016. Experienced paramedics stationed close to the participating major trauma centre were asked to evaluate the device with a view to obtaining a minimum of 20 cases of iTClamp use to determine its suitability.

Paramedic participants were trained by the manufacturer before being provided with two iTClamps. After every application, the evaluating paramedic produced an unstructured reflective account and completed an evaluation questionnaire.

Paramedics who used the iTClamp™50 found it enhanced their ability to quickly control external haemorrhage in difficult anatomical areas and could be used as part of a major haemorrhage control strategy. Overall, paramedics felt it was quick and easy to use following a short training session.

Keywords
emergency medical services; haemorrhage; wounds and injuries

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Introduction

It has long been accepted that uncontrolled haemorrhage is a leading cause of early death in trauma patients, with the majority of deaths occurring in the pre-hospital setting (Mottet, Filipis, Longsetty, & Atkinson, 2014). Therefore, ambulance services play a vital role in delivering early effective treatment. Since the inception of the northern trauma system and the major trauma bypass in April 2012, ambulance crews have been able to bypass local trauma units (TUs) and deliver patients to definitive care at designated major trauma centres (MTCs) based on physiological, anatomical assessment and also a group of special circumstances including age and pregnancy.

Pre-hospital practitioners are in a unique position to influence and initiate patient care in cases involving significant haemorrhage. Recent advances in prehospital haemorrhage control have resulted in ambulances now routinely carrying haemostatic dressings, modular bandages, tourniquets and tranexamic acid (TXA). Within the North East Ambulance Service (NEAS), these items are contained in a major trauma pack, along with chest seals, and are available on all front line ambulances.

Most cases of haemorrhage can be dealt with using standard dressings, tourniquets and haemostatic agents. However, some difficult anatomical areas such as the head, neck, axilla and junctional areas continue to be problematic, as it is challenging to apply tourniquets or trauma pressure dressings to these areas effectively.

The iTClamp™50 was developed by Innovative Trauma Care™ as a temporary wound/skin closure device that quickly controls bleeding, by closing the skin edges of a wound and creating a temporary contained haematoma, until definitive surgical repair. The haematoma within the wound pocket remains contained and does not extend through surrounding tissue. Once the pressure in the haematoma equilibrates with the bleeding source, the blood flow is stopped and the clot begins to form (Mottet et al., 2014). A porcine study conducted by the inventor demonstrated that the device was 100% effective in controlling haemorrhage from a lethal femoral artery injury, compared to 60% control with standard gauze (Filips, Logsetty, Tan, Atkinson, & Mottet, 2013).

Aims

The aim of this study was to evaluate the inclusion of the iTClamp™50 into the existing NEAS major trauma pack. A service evaluation of the iTClamp™50 was requested by the NEAS medical director and consultant paramedic and with their approval, a standard operating procedure and service evaluation was designed and conducted by the senior trauma paramedics (Supplementary 1 and 2). This evaluation aimed to record a minimum of 20 iTClamp™50 cases. We sought to enhance patient care in major haemorrhage control and wound closure in difficult anatomical areas.

Method

Following consultation between NEAS, local hospitals and iTraumaCare™ representatives, a service evaluation was designed to investigate and evaluate the iTClamp™50 in routine ambulance practice. There are two MTCs located in the North East region, James Cook University Hospital (JCUH) in Middlesbrough, which covers the south of the region and the Royal Victoria Infirmary (RVI) in Newcastle upon Tyne, which covers the north of the region. Currently the majority of major trauma cases are seen by the RVI in Newcastle and it was decided that the evaluation would be centred around this hospital.

Sixty-four paramedics were invited to evaluate the iTClamp™50 (Table 1). All of these paramedics were experienced clinicians with an interest in trauma and had participated in previous NEAS clinical trials or clinical evaluations. The majority were members of the hazardous area response team (HART) as they attend a significant proportion of trauma cases in the North East region.

<table>
<thead>
<tr>
<th>Role</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>HART</td>
<td>42</td>
</tr>
<tr>
<td>Road paramedic</td>
<td>18</td>
</tr>
<tr>
<td>Senior trauma paramedic</td>
<td>3</td>
</tr>
<tr>
<td>Consultant paramedic</td>
<td>1</td>
</tr>
</tbody>
</table>

HART: hazardous area response team.

The majority of the 18 front line paramedics worked around the RVI MTC, which has a busy urban area and a large range of potential cases. In addition, following scrutiny of a major trauma audit conducted in NEAS, an outlying rural station was also included in the evaluation since a significant number of agricultural accidents and road traffic collisions (RTC) occurred in this area.

Training

Each member of staff attended a 3-hour interactive training session hosted by the NEAS trauma team and delivered by iTraumaCare™ representatives, including the science and theory of haemorrhage control and discussion of previous case studies where the iTClamp™50 had been used. Within this session the scope of the device was discussed, including the type of injury and anatomical locations that were suitable for the device to be utilised with (see Supplementary 3 for the clinical training competency checklist).

It was envisaged that 20 cases obtained over a 6-month period would be an adequate number to evaluate and inform possible implementation into the NEAS trauma system. Staff were given two devices each and asked to report back to the NEAS senior trauma paramedics any cases where the device had been utilised. An evaluation questionnaire, supplied by the manufacturer, was then passed to the user to complete. Each member of staff
then wrote a small unstructured reflective piece of work, detailing their use of the iTClamp™50, giving feedback and judging the effectiveness of the device. Each case was reviewed by the senior trauma paramedics; any concerns for patient safety would be identified and evaluated. The evaluation could be suspended on the advice or request of the medical director or consultant paramedic.

Results
There were 24 recorded cases between July 2014 and February 2016, with 13 devices used by road paramedics, six by HART paramedics and five by senior trauma paramedics. A summary of use by anatomical location is shown in Table 2.

Table 2. Summary of iTClamp use by anatomical location.

<table>
<thead>
<tr>
<th>Anatomical location</th>
<th>Number of uses</th>
</tr>
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<tbody>
<tr>
<td>Scalp</td>
<td>8</td>
</tr>
<tr>
<td>Lower limb</td>
<td>5</td>
</tr>
<tr>
<td>Neck</td>
<td>4</td>
</tr>
<tr>
<td>Upper limbs</td>
<td>4</td>
</tr>
<tr>
<td>Forehead</td>
<td>2</td>
</tr>
</tbody>
</table>

Scalp
There were eight recorded scalp wound cases, mainly from mechanical falls, and one case involving farming machinery.

Case A
Case A involved a patient with a deep 10 cm laceration to the scalp. The wound was bleeding profusely and the blood loss at this time was estimated at 150 ml. Although dressings were initially used to manage the wound, haemostasis had not been achieved. On arrival of the trained paramedic, the iTClamp™50 was then applied and the crew were able to close the wound and visually inspect it for any further bleeding. The crew managed to achieve rapid control of bleeding and did not feel it was necessary to apply a second device. The patient reported a small stinging sensation on application of the device, but once the device was in place, noted a feeling of pressure, but no further pain. On arrival at hospital, emergency department (ED) staff requested the iTClamp™50 be removed and the wound inspected. It was noted at this time that when the device was removed the wound had begun to clot and no further bleeding occurred.

Of the eight recorded scalp laceration cases, there were two instances of arterial bleeding, uncontrolled with standard gauze and pressure. In both of these cases staff commented on the speed of haemorrhage control, and the ability to visualise the wound, being of significant benefit.

Case B
In Case B, two iTClamp™50s were used due to the length of the wound. The manufacturer’s European reference manual (Filips, 2013) indicates that the iTClamp™50 should be used in cases where skin approximation can be achieved. The staff reported that in these cases the wounds were able to be approximated by immobilising the leg; full haemorrhage control was then achieved.

Case C
Case C involved a traumatic cardiac arrest due to a penetrating injury, where an ongoing resuscitation effort by emergency service personnel was being carried out. A large wound was detected by paramedics, the iTClamp™50 was applied effectively and a return of spontaneous circulation (ROSC) was achieved. The crew felt that the application of the device had served as an effective tool during the resuscitation effort.

Neck
Each of the four cases involving the neck were caused by an assault with a knife; three of the cases were described as incised wounds, and one described as a penetrating wound. One of the incised wounds was recorded as being 30 cm in length from front to back, with underlying structures, including arteries, visible. After applying two devices to the wound, minimal bleeding was reported. The staff felt that in this case, a third iTClamp™50 could have been utilised, but were limited by the number they had available. Although the patient was intoxicated, they reported a small amount of pain on application, but no further pain on transport to hospital. Once again the paramedic noted that the speed of haemorrhage control and ease of application were of most benefit.

Arms
The four reported cases of iTClamp™50 uses on the forearms also reported the mechanism of injury as wounding by knives.
We evaluated the inclusion of the iTClamp™50 in the NEAS major trauma packs and found that in the majority of cases the device was able to quickly control haemorrhage in difficult anatomical areas. Of the 24 recorded cases there was only one reported case where the iTClamp™50 had been used in an incorrect anatomical area. Although the wound was not considered to be serious in nature, it was described as being on the patient’s back, below the scapula. In this instance the wound edges could not be approximated due to this area being under high tension and therefore not suitable for the iTClamp™50 to be used. After a brief discussion with the paramedic, further training and clarification was offered and no further incorrect applications were recorded.

Initially members of staff who were chosen to evaluate the iTClamp™50 viewed the device with a certain amount of scepticism. Following comprehensive training including practical and theory elements, they were given two iTClamp™50 devices to evaluate in routine ambulance practice. A frequently asked question that arose from staff at training events concerned possible complications arising from the haemostoma, such as compartment syndrome. Margheritini and Rossi (2011) explain that blood vessels in the compressible areas run in fascial compartments, which limits the size of the haemostoma.

In addition to this, distal perfusion is maintained if the artery is not completely transected (Atkinson, 2013).

Having considered the reflective accounts produced by the staff, it seemed there was some hesitation in applying the device for the first time. Once the device was in place and haemorrhage control had been achieved with a successful outcome, we noted that staff were happy to use the device or consider using it in subsequent cases.

Feedback provided by paramedics after the evaluation indicated that they would all definitely use the iTClamp™50 again. Even in the minority of cases where the device did not gain full haemorrhage control, the staff would still recommend the device. It should be noted that in cases involving alcohol or when the patient was reported as being in an agitated state, definitive haemorrhage control could not always be achieved. These findings would need to be considered in any future training, and standard haemorrhage control methods may need to be employed.

Many of the staff used the device on multiple occasions and commented on the ease of application and speed of haemorrhage control being the most important factors.

**Discussion**

We evaluated the inclusion of the iTClamp™50 in the NEAS major trauma packs and found that in the majority of cases the device was able to quickly control haemorrhage in difficult anatomical areas. Of the 24 recorded cases there was only one reported case where the iTClamp™50 had been used in an incorrect anatomical area. Although the wound was not considered to be serious in nature, it was described as being on the patient’s back, below the scapula. In this instance the wound edges could not be approximated due to this area being under high tension and therefore not suitable for the iTClamp™50 to be used. After a brief discussion with the paramedic, further training and clarification was offered and no further incorrect applications were recorded.

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Angiographic images obtained during a pre-clinical cadaver study showed that once stasis is achieved and the clot forms, the clot remains reasonably small and stable. In addition to this, distal perfusion is maintained if the artery is not completely transected (Atkinson, 2013).

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**Limitations**

The limitations of this piece of work included the small sample size; the evaluation was based upon a 24-case
series. We were unable to identify a more detailed demographic. We were also unable to follow up on the final outcome in many of the cases and only anecdotal evidence was reported back to the senior trauma paramedics. The reflective pieces of work produced by the paramedics were not in a structured format and staff were allowed to create an unstructured account. The evaluation relied upon staff reporting any uses of the device back to the senior trauma paramedics; a more comprehensive data collection process could have been devised. The future cost of implementing the iTClamp™50 and any training will need to be considered. Many of these points could be addressed in more detail if any future service evaluation or clinical trial is undertaken.

Conclusion

This paper shows that the paramedics who used the iTClamp™50 found it enhanced their ability to quickly control external haemorrhage in difficult anatomical areas and could be used as part of a major haemorrhage control strategy. Overall, paramedics felt it was quick and easy to use following a short training session.

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Sonia Byers: Research and Development Manager – reviewed article.

Author contributions

GS: Senior Trauma and Research Paramedic – lead author, co-ordinated project, collected data, produced article.
LT: Senior Trauma Paramedic – assisted in data collection, co-authored article.
CD: Senior Trauma and Research Paramedic – assisted in data collection, co-authored article.

Conflict of interest

iTraumaCare™ supplied a number of devices for the NEAS service evaluation and also supplied training sessions for staff. These were hosted by the NEAS Senior Trauma Paramedics. There was no funding attached to the service evaluation. Data collection and data analysis were independent of iTraumaCare™.

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References