Clinical Research

A systematic review of the use of tourniquets and topical haemostatic agents in conflicts in Afghanistan and Iraq

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Abstract

Introduction
The recent conflicts in Afghanistan and Iraq have seen increased use of tourniquets and topical haemostatic agents in the management of battlefield trauma. The aim of this paper is to review the available evidence for their efficacy and continued use.
Methods
A systematic review of the medical literature published as a consequence of conflicts in Iraq in Afghanistan was conducted to determine the clinical outcomes from the use of tourniquets and haemostatic agents for haemorrhage control in limb extremity injury.
Results
Studies were retrospective cohort or prospective observational studies by design. None were eligible for meta-analysis and control groups were rarely available for ethical reasons. Despite methodological limitations, tourniquets were shown to save lives if applied prior to the onset of shock or in a pre-hospital setting. Topical haemostatic agents were shown to be useful adjuncts in haemorrhage control with small numbers of complications.
Conclusion
In the military setting, tourniquet use in extremity trauma improves survival when used prior to the onset of shock. Topical haemostatic agents provide additional means of haemorrhage control, though further studies to identify the most effective types are necessary. Adequate training and protocols for use must be implemented to prevent complications through use.

Introduction

"There are two groups of people in warfare - those organised to inflict and those to repair wounds - and there is little doubt but that in all wars, the former have been better prepared for their jobs" (1).

Hippocrates is credited with saying that "war is a surgeon's best training ground" (2). Historically, military conflict has led to changes in military and civilian medical care. The concept of treating military casualties has not changed in decades; it involves safe, expeditious evacuation from the field, control of haemorrhage, and prevention of death secondary to infection (3,4).

The conflicts in Afghanistan and Iraq saw an increasing use of tourniquets and topical haemostatic agents in the management of battlefield haemorrhage. A number of changes in practice developed during these recent conflicts. This paper aims to assess the evidence supporting these developments and evaluates these two trauma techniques with particular focus on the 'Platinum Ten Minutes'. Advanced management of airway emergencies, transfusion protocols, serious head injuries and massive thoracic haemorrhage were not considered within the scope of this article.

Methods

A systematic review of the literature was conducted to determine the use of tourniquets in limb extremity injury and haemostatic agents for haemorrhage control during the Iraq and Afghanistan conflicts. The search was performed independently by two reviewers using Medline, Embase, and Cochrane databases to identify all reports published between 2001 and 2014. Full details of the search strategy used can be found in Table 1.

Pre-hospital tourniquets	Topical haemostatics
1. Afghanistan 2. Afghan Campaign 2001-2014 3. Iraq War, 2003-2011 4. Iraq 5. 1 or 2 or 3 or 4 6. Military Medicine 7. War 8. Combat.mp. 9. Battle.mp. 10. Conflict.mp. 11. 6 or 7 or 8 or 9 or 10 12. Tourniquet.mp. or Tourniquets 13. Lower Extremity 14. Arm Injuries 15. Leg Injuries 16. Limb injury.mp. 17. Limb Salvage 18. Hemorrhage 19. Haemorrhage.mp. 20. 13 or 14 or 15 or 16 or 17 or 18 or 19 21. 5 or 11 22. 21 and 20 Limit 22 to (English language and humans) Limit 23 to yr="2001 - 2014" [57]	1. Afghanistan 2. Afghan Campaign 2001-2014 3. Iraq War, 2003-2011 4. Iraq 5. 1 or 2 or 3 or 4 6. Military Medicine 7. War 8. Combat.mp. 9. Battle.mp. 10. Conflict.mp. 11. 6 or 7 or 8 or 9 or 10 12. 5 or 11 13. Topical.mp and Bandages 14. Hemostasis 15. Haemostasis.mp. 16. Hemostatics 17. Haemostatics.mp 18. Coagulopathy.mp. 19. Disseminated Intravascular Coagulation 20. Chitin 21. Fibrin 22. Zeolites 23. 13 or 14 or 15 or 16 or 17 or 17 or 18 or 19 or 20 or 21 or 22 24. 12 and 23 Limit 24 to (English language and humans and yr="2001 -Current") [146]

Table 1. Search strategies used for this review.

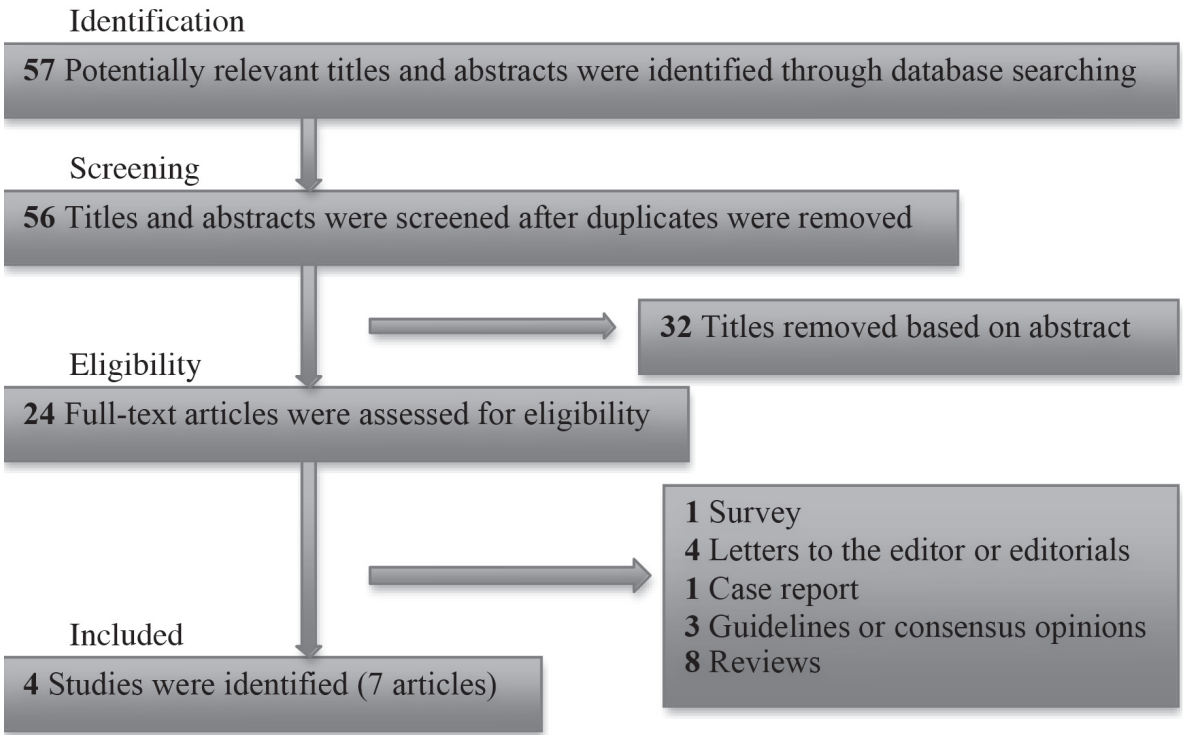

Figure 1. Studies included for the use of pre-hospital tourniquets.

Each study was assessed for eligibility for inclusion in the systematic review. All cited articles within each paper were reviewed and any additional studies identified to be relevant were included at this stage.

All reports published between 2001and 2014 were considered for inclusion in order to capture all studies carried out within the time frame of the Afghanistan and Iraq conflicts. Full text, English studies of any type including e-publications were included. There were no problems with access to articles due to military censorship.

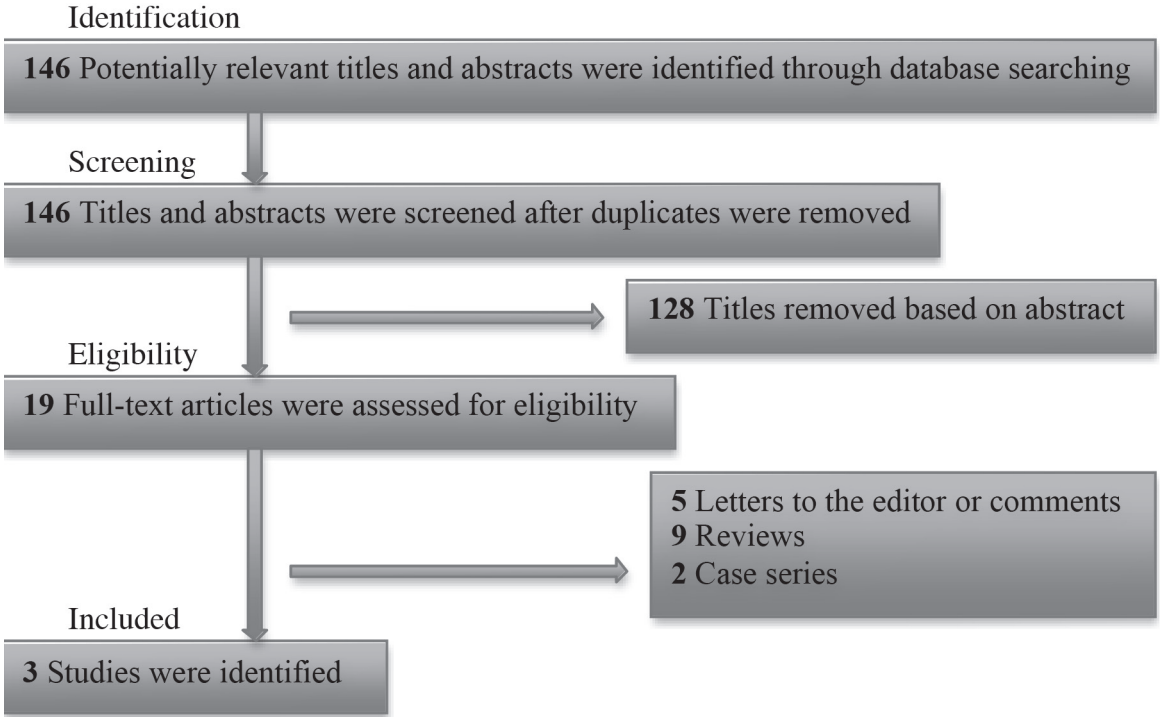

Figure 2. Studies included for topical haemostatics.

Two independent reviewers carried out assessment of eligibility in an un-blinded standardised manner. Where there were disagreements between reviewers these were resolved by consensus. Reviews, editorials, comments and letters to the editor were excluded.

Pre-hospital tourniquets

Studies describing the use of tourniquets as a pre-hospital intervention for extremity injury or haemorrhage control were included (Fig 1). Comparison when appropriate was made with those who were not treated by tourniquet. Primary outcome was all-cause mortality; secondary outcomes were effectiveness of tourniquets in controlling haemorrhage, secondary amputation and complications directly due to tourniquet use.

Topical haemostatic agents

All studies using topical haemostatic agents for haemorrhage control were included (Figure 2). Comparison was made to alternative treatments, and outcome measures were effective haemorrhage control and complications, specifically, thermal injury and infection as a result of use.

Results

Tourniquets

The use of tourniquets has varied considerably in history. With the recent conflicts in Iraq and Afghanistan there has been a re-emergence of clinical decision making with regard to limb extremity management. From 2006 until April 2013, 291 limb amputations were performed on UK service personnel in Afghanistan and Iraq (5).

Characteristics of included studies

Seven studies were suitable for inclusion: four prospective observational studies and three retrospective analyses in which tourniquets had been used for the treatment of extremity haemorrhage in a pre-hospital setting (6-12). Patient characteristics such as demographics and injury severity scoring were similar. Due to heterogeneity (methods and outcome) meta-analysis was not possible. Follow up was between 0.5 and 860 days.

Risk of bias in included studies

No patients were randomised to treatment groups. The largest study produced four papers, prospectively collating data by two authors across a twelve-month period (6-9). Areas of potential bias in the intervention arm include the

use of differing tourniquet styles: for example, the Combat Application Tourniquet (CAT) was introduced during the study period. Thus there was no standard treatment, because differing designs, including homemade tourniquets, may have produced differing outcomes in terms of effectiveness and complications. Other confounding factors arise from the nature of military trauma itself – for example, torso or head injury may have a greater impact on the patient's survival than extremity injury.

Participants

All patients were injured during combat in Iraq or Afghanistan. Male patients predominated. All study participants were adults, apart from sixteen children included in one of the series. Nationality varied across studies and included individuals from North Atlantic Treaty Organisation (NATO) countries and local populations. Injury Severity Scores (ISS) were not universally reported in all appraised papers.

Intervention

Four studies by Kragh *et al*. reported on survival based on, and morbidity associated with, tourniquet use (6-9). Subgroup analyses assessed the geographical location of tourniquet placement, i.e. pre-hospital or Emergency Department, and whether the tourniquet was placed prior to or after the onset of shock (defined as the absence of or a weak radial pulse in a limb without injury or a tourniquet applied).

In their series, Kragh *et al*. report outcomes for 499 patients with 862 tourniquets applied to 651 limbs. Tourniquets placed prior to the onset on shock improved survival - 90% (429/477) when compared to 18% (4/22) who had tourniquets placed after developing signs of shock (absence of a radial pulse). Subgroup analyses were undertaken of five casualties, not within the original study group of 499 patients but who had isolated extremity injuries in which tourniquets were not placed. This group of five casualties had a 0% survival rate. They were compared to a group of thirteen matched cohorts from within the study group with similar injuries. Their survival percentage was 87% (87% (10/13) vs. 0% (0/5), $P < 0.007$). The authors concluded that early tourniquet placement in the pre-hospital setting and in the absence of shock improved survival, although this was not statistically significant.

Beekley *et al*. looked at effectiveness in terms of haemorrhage control and patient outcome following tourniquet use (10). Patients with partial foot, hand or digit amputation and those associated with severe trunk or head injuries were excluded. Two groups of patients with ISS >15 were identified: those with pre-hospital tourniquets applied (67 patients), and those with no tourniquet applied (98 patients). Records of the effects of interventions (tourniquet or field dressing) were available for 42/67 (63%) and 28/98 (28%). Of those with pre-hospital tourniquets, adequate control occurred in 83.3% compared to 60.7% without tourniquets.

Vascular reconstructions were completed in 52% of the non-tourniquet group compared to 29% of those with tourniquets. This suggests that there were fewer traumatic amputations and therefore more salvageable limbs in the non-tourniquet group. For those patients without signs of bleeding on arrival, but with injuries requiring primary amputation or debridement amputations, 92% had tourniquets compared to 50% without.

Brodie *et al*. studied the prevalence of tourniquet use in military populations treated in UK field hospitals during the Iraq and Afghanistan conflicts and later included all UK personnel evacuated from the military theatre. Data was collated retrospectively from the UK Joint Theatre Trauma Registry (JTTR). The authors attempt to assess tourniquet use, effectiveness in haemorrhage control and complications as a result of use (11). From 1375 cases, 70 casualties had tourniquets applied as part of their treatment (107 tourniquets). 61/70 (87.1 %) patients survived their injuries. Three were killed in action (prior to arrival at treatment facility but with basic first aid administered), four died of wounds and two died due to non-hostile action. Of these deaths, six had an ISS of 50 and would not have been expected to survive. The authors demonstrate through data a twenty-fold increase in use following the introduction of CAT tourniquets as personal first aid equipment, but stop short of identifying whether all tourniquets were placed in accordance with guidelines.

Clasper investigated whether pre-hospital application of a tourniquet resulted in increased limb morbidity following significant ballistic injury (12). Inclusion criteria were patients with lower limb fracture either with or without pre-hospital tourniquet application. 60 patients were assessed (25 in the pre-hospital tourniquet group and 35 in the control group). Each group was reduced to 22, although it is not clear by what method and to what end. In the pre-hospital tourniquet group, 19/22 patients were recorded as suffering complications compared to 15/22 in the control group. Major complications occurred in ten patients in the pre-hospital group and four in the control group, with deep infection in 7/10 and 1/4 ($p<0.05$) respectively. This was statistically significant, but no reason for this has been identified. Both groups were matched for ISS, time to surgery, and type of bone injured. There is no data offered as to the extent of each limb injury and, before concluding that deep wound infections are directly associated with tourniquet use, it would be prudent to analyse the extent of the limb injuries requiring a tourniquet and those which did not.

Kragh *et al*. found no association between prolonged tourniquet use and nerve palsies, pain, renal failure, clots or myonecrosis (6-9). There were nine reports of transient nerve palsy in 651 limbs, 1.4% of all patients (all symptoms resolved by three days except in one patient who was transferred with no follow-up data). No patients with two tourniquets applied side by side developed nerve palsies. Of those with a tourniquet time exceeding three hours, 60% had an amputation. However, there is no attempt to qualify whether amputation would have been necessary regardless of tourniquet use. More data is given for the patients who had tourniquets applied for less than two hours. Of 67/77 who required limb shortening, no procedures were performed for reasons associated with tourniquet application. Overall complication rates were very low at 1.7%. Beekley et al. reported no complications from tourniquet use (10).

Topical haemostatic agents

Many injuries seen in military trauma occur in junctional areas where tourniquets cannot be applied (13). Gray originally described human fibrin as a topical haemostatic in 1915 (13). It was used with varying success in the First World War but discarded after World War Two due to concerns surrounding infection transmission. More recently, haemostatic agents, which can be applied to bleeding wounds, have been mainly used in the conflicts in Israel/Palestine, Iraq and Afghanistan (14).

Characteristics of included studies

One prospective observational study and two retrospective analyses where topical haemostatic agents had been used for the treatment of extremity haemorrhage were identified (15-17). Differences in primary and secondary outcomes as well as inclusion and exclusion criteria prevent meta-analysis. Follow-up data was not stated in any of the studies presented.

Risk of bias in included studies

No patients were randomised to treatments due to the nature of the studies. The studies included alternative methods of haemorrhage control alongside topical haemostatics. The effects on haemorrhage control solely due to topical haemostatics may be overestimated.

Participants

All patients were injured during combat in Iraq or Afghanistan. Demographic and injury severity data for participants was limited, and reported in only one study.

Effects of interventions

King *et al*. (prospective observational study) assessed nineteen consecutive patients who had Modified Rapid Deployment Haemostat (mRDH, a topical haemostatic bandage) applied to bleeding wounds (30 dressings) (15). These bandages were used as an adjunct prior to definitive haemorrhage control while coexisting injuries were being treated in the emergency setting. The authors documented cessation of bleeding with application and less coagulopathy or re-bleeding after dressing removal. Dressings were used in cavities as well as on surface wounds. Unfortunately, coagulopathy was assessed clinically due to lack of laboratory support and application times were not always recorded. Only one mRDH dressing was applied in the pre-hospital setting. However, six patients had QuikClot® dressings applied in the field. The authors report that the dressings led to complete cessation of bleeding in 14/19 (74%) cases and a reduction in bleeding in 2/19 (10.5%). Re-bleeding was noted in 3/19 despite complete cessation prior to removal. The authors concluded that this was due to clot disturbance and may have been time-related. They did not note a reduction in efficacy in those patients presumed to be coagulopathic. No application-associated complications were reported.

In a survey completed by hospital medical clinicians after the use of haemostatic bandages in theatre, 64 cases are reported in which two types of dressing were used, HemCon® and QuikClot® (16). In 42 patients who continued to bleed after standard gauze was applied cessation or reduction of bleeding was reported in 97%, and in 100% following application of a haemostatic dressing. Only 7% of these wounds were deemed to have evidence of arterial bleeding recorded by clinicians although data was lacking in 24%. Cox *et al*. describe the use of HemCon® and QuikClot® in a single-centre, retrospective cohort review (17). In a six-month time period, 44 patients had 50 dressings applied. Mechanisms of injury, ISS, source of bleeding and outcomes were recorded. 7/8 with field-applied haemostatic dressings had extremity injuries with a tourniquet applied, which was controlling the bleeding. The addition of a tourniquet makes the use of dressings in these cases difficult to assess. However, the authors stated that haemorrhage was adequately controlled with haemostatic dressings in all three patients who re-bled after tourniquet removal. With regard to efficacy, the authors gave only a blanket statement from the attending surgeon that they were 'successful in achieving haemostasis.' Three complications were recorded: a surgical site infection after application of HemCon® and two superficial burns after QuikClot® application. The authors state that the complications did not have a significant impact on patient outcome.

Discussion

Tourniquets

Randomised controlled trials are almost impossible to conduct in combat medicine. The United Kingdom (UK) and United States (US) military have developed performance improvement programmes (such as the Joint Theatre Trauma Registry) in an attempt to define standards of care through expert opinion and consensus statements

(18). Well-designed, prospective non-randomised cohort studies probably represent the best available evidence from military research.

Epidemiological studies from Iraq and Afghanistan add to the evidence that exsanguination from extremity injuries is a cause of potentially preventable death (19, 20). However, over time the anecdotal consensus opinion for tourniquet use in limb injury was that it should be a treatment of last resort. There were concerns that more lives and limbs have been lost as a direct result of their improper use compared to the number of additional lives saved with proper use (21). Recent evidence and expert opinion now suggest that tourniquet use prior to the onset of shock improves survival. Complications directly attributable to tourniquets are low, principally occurring with prolonged tourniquet time. However, for patients with fractures requiring reconstruction, tourniquets may add to the challenge of treating these complicated injuries. Correct application is necessary, avoiding venous tourniquets (venous stasis without arterial compression leading to swelling of the limb) that may cause compartment syndrome. Training to ensure complete obliteration of distal pulses when the limb is intact would reduce the risk of this occurring. Other concerns, including on-going bleeding from limbs with tourniquets applied, have been noted in previous studies. The Norwegian military (Iraq 1991) noted continuous bleeding with tourniquets applied, but a reduction after direct pressure bandaging was used instead of tourniquets in a second study period (22). This paper was published in a time when tourniquets were 'home made' and no protocols were in place for safe use.

Studies from the Israel/Palestine conflict have shown similar results to those of Kragh *et al.* The Israeli Defense Force reintroduced the use of tourniquets in 1997 to all soldiers not medically trained. A study by Lakstein *et al*. of 550 injured soldiers and civilians showed that tourniquet use prevented death from exsanguination (23). Despite strict criteria for their use and removal, soldiers were over-zealous with the use of tourniquets, but even with high rates of over-application there were very few complications. However, some circumstances such as assessing a patient in the dark under fire may lead to understandably inappropriate use: therefore, reassessment is the key to preventing complications, and stringent protocols must exist. Tourniquet conversion (removing the tourniquet without subsequent bleeding) was successful in 76% of patients (13/17) and 78% of applications were effective with no cases of death from uncontrolled limb haemorrhage. Despite guidelines, none of the presented studies mentioned tourniquet conversion. In the study by Kragh *et al.*, the authors noted an increase in fasciotomy rates after tourniquets were issued to soldiers, but concluded that this was due to the increase in the number of lives and limbs saved as a result and not necessarily a direct correlation with tourniquet use *per se* (6-9).

Follow-up in all studies was short, possibly due to the nature of evacuating casualties from military theatre as soon as possible for definitive treatment in their home countries. As such there is no data regarding long-term outcomes, amputation-free survival or the functionality of non-amputated limbs.

Topical haemostatic agents

Topical haemostatics have been shown to be effective for external haemorrhage in animal models but few human trials exist (24, 25). Not all haemostatics are equally efficacious and in several there are concerns with regard to thermal injury (26). Early forms of QuikClot® were associated with intense thermal reactions when applied to blood but newer forms are less exothermic. Despite these improvements, cases of thermal injury are still being reported, albeit in low numbers. Only Hemcon® has undergone human testing prior to release and many authors have highlighted concerns about the reproducibility of results seen in animal studies (16, 27). The ideal agent would be easy to use, safe, durable and effective. It appears that this agent has not yet been developed: however, there is clearly a role for the use of these agents in battle to control haemorrhage. Indeed, none of the reported studies have robustly proven their efficacy. Animal studies have shown QuikClot® to be efficacious against bleeding in mixed arterial and venous bleeding, but not in severe arterial bleeding. The largest study in humans was conducted in a military and civilian setting (28). Due to the mixed population it is not presented in this systematic review. 103 cases of QuikClot® use demonstrated an overall efficacy of cessation of bleeding of 92%. A failure rate of 8% was recorded, which occurred in moribund patients with significant injuries. A 3% burn injury rate (requiring skin grafting) was also reported. Use inside a body cavity was reported in twenty patients (19%); fibrosis occurred within the peritoneal cavity of one patient when used in this manner. It is interesting to note that, as in the UK, the recommendations of the US Committee on Tactical Combat Casualty Care (CoTCCC) are that control of external haemorrhage should occur in a stepwise manner with pressure dressings, tourniquets, and combat gauze (a new form of QuikClot®) in various application formats (29).

Overall, considering the difficulties and limitations of studies in battlefield trauma, the best available evidence suggests there is a rationale for on-going use of tourniquet and haemostatic agents in a combat setting. However, what about civilian trauma? The injury patterns seen in these studies are unique to war, typically blast injuries from improvised explosive devices (IEDs). Extremity vascular injuries in civilian populations have been identified in less

than 5% of all trauma admissions (30). Overall mortality from traumatic amputations and extremity injury is low in civilian populations. However, increased mortality rates are seen in those with blunt extremity injury, accounting for 20% of all trauma deaths (30). These figures do not specify exsanguination as the cause of death and it is unlikely that there would be significant improvement in mortality figures solely through implementing tourniquet use. Strict protocols for use and regular training would be necessary to avoid problems arising as a result of infrequent use when experience is limited. Advanced Trauma Life Support (ATLS) recommendations are that tourniquets can be used in appropriate circumstances (21).

Conclusions

In the military setting, tourniquet use in extremity trauma improves survival when used prior to the onset of shock. Topical haemostatic agents provide an additional means of haemorrhage control, though further studies to identify the most effective types are necessary. Adequate training and protocols for use must be implemented to prevent complications through use in civilian trauma.

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