



The safety and efficacy of improvised tourniquets in life-threatening hemorrhage: a systematic review

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Abstract

Objective The increased incidence of mass casualty incident (MCI) with penetrating injuries in the civilian setting creates a call for implementing devices, such as a tourniquet (TQ), in civilian first aid. Bystanders could act as immediate responders after an MCI in order to prevent a victim from exsanguination using direct pressure or commercial tourniquets (C-TQ). Reports have shown that immediate access to C-TQs was not available and bystanders used objects available at the trauma scene to make an improvised tourniquet (I-TQ). The aim of this systematic review of literature was to summarize the existing literature on designs, efficacy and safety of I-TQs.

Methods A systematic review of the literature was performed. Bibliographic databases PubMed, EMBASE.com and Cochrane Library were searched. All types of original studies about I-TQ's were included. Review studies, excerpts from textbooks or studies with TQs applied during elective surgeries were excluded.

Results Twenty studies were included. In both simulated experiments and real-life situations, I-TQs outperformed commercial TQs (C-TQ) regarding success rate. Of the I-TQs, the band and windlass design performed most consistently. Although lacking any statistical analysis, there was no reported difference in adverse events between I-TQs and C-TQs.

Conclusion The use of- and training in I-TQ by civilian immediate responders is not recommended because of limited efficacy and safety concerns; direct pressure is a viable alternative. However, I-TQs may save lives when applied correctly with proper objects; therefore, future studies regarding the best design and training in application of effective and safe I-TQs should be encouraged.

Keywords Tourniquet · Improvised · Exsanguination · Hemorrhage · Hartford consensus · Bystander

Introduction

Mass casualty incidents (MCI), such as terrorist attacks occur with increasing frequency. Analyzing the data as presented by the Global Terrorism Database of terroristic events occurring in North-America, Western Europe and Australasia &

Oceania, a marked increase of 105 events in 2011 to 385 in 2017 is seen [1]. In Europe recent years saw a surge of these events, such as the Paris attacks, Manchester bombing, Norway Utøya shooting and Brussels Airport bombing. In the United States of America (USA), between 2011 and 2018, there was an increase from 13 to 97 school shootings, with an even greater increase of casualties related to these events (4–56) [2]. In 2002, the US military implemented a new method of treating the wounded on the battlefield: tactical combat casualty care (TCCC) which encompasses a widespread use of tourniquets. Earlier, a tourniquet (TQ) was seen as a last resort with a high risk of added morbidity [3]. After implementing TCCC, a drastic decrease of 67% of combat casualties by extremity exsanguination was seen [4]. The aforementioned increase in MCIs created a call for implementing the military experience in civilian emergency services. To utilize this military experience a conference was organized in 2013 for public

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security service representatives in Hartford, USA to develop a strategy to increase the survivability of the public in mass civilian attacks. During the conference it became clear that the strict method of waiting for the tactical units to suppress the threat before allowing emergency medical service (EMS) personnel in the danger zone, creates a timeframe in which mortality and morbidity increase due to uncontrolled hemorrhage and shock [5]. The Hartford consensus proposed a new system for approaching mass shooting events, using the acronym **THREAT** [6]. **T**hreat suppression. **H**emorrhage control using TQ's and hemostatic dressings. **R**apid **E**xtrication to safety. **A**ssessment by medical providers. **T**ransport to definitive care. In addition to this system; a new group of potential responders were identified: the public present at the trauma scene (so-called bystanders) can act as immediate responder directly after an attack. This group has not yet been incorporated in training but could be of considerable value when educated in hemorrhage control [7].

Direct pressure is the first and most simple step, but in situations where direct pressure is not a feasible option, the lifesaving effect of a TQ has become more apparent. In the past decade the experience with commercially designed TQs (C-TQ) increased due to widespread use by the military. These previously mentioned bystanders that might prevent the victim from exsanguination are unlikely to have medical equipment such as C-TQs or hemostatic gauzes to their immediate availability. Nevertheless, potential tools available at the trauma scene such as cloths, bandages, etc., can be used to achieve hemorrhage control. These tools can be utilized, using the principle of C-TQs, to exert enough circular pressure on the limb to occlude the arteries. Various papers report the use of improvised tourniquets (I-TQ) in the civilian setting, some effective and others ineffective or even increasing hemorrhage [8–13]. Various designs of C-TQ and I-TQ were encountered, and the most common are summarized in Table 1. The variety in design and materials used may elucidate the degree of efficacy. We impose that bystanders can bridge the gap from time of injury to arrival of (para) medical care in life-threatening hemorrhage possibly by using an improvised tourniquet. The aim of this systematic review was to summarize the existing literature on design, efficacy and safety of improvised tourniquets and assess whether an optimal design can be found to be implemented in the education of bystanders to increase survivability in MCI's.

Methods

Search strategy

A systematic review of the literature was performed according to the preferred reporting items for systematic

Table 1 Tourniquet characteristics

Commercial tourniquets		Improvised tourniquets	
Type	Characteristics	Type	Characteristics
Combat application tourniquet (CAT)	Band and windlass design sturdy belt of approx. 1 inch wide with a single routing buckle and an incorporated dowel and dowel securing clip	Band-and windlass	A cloth wrapped around the limb with a dowel of sorts (stick, clamp, chop-sticks) incorporated into the knot. Then the dowel is twisted to apply more pressure
Special operation forces tactical tourniquet (SOFT-T)	A similar design to the CAT, band and windlass	Silicone surgical tubing	Elastic silicone tubing stretched and wrapped around the limb several times and tucked in on itself or secured with a clamp. Which can be used to twist the knot to tighten the tubing further
Stretch wrap and tuck tourniquet (SWAT-T)	A wide silicone strap with ovals printed on both sides. Designed to wrap several times around the limb. As it is stretched the oval deforms and becomes a circle, indicating enough circular pressure is achieved. The TQ is then tucked beneath itself	Belts/wires/cloths	Anything wrapped around the limb with no elastic properties. Tied with a knot or in case of the belt using the buckle
Pneumatic emergency medical tourniquet	A wide pneumatic cuff with bellow. Designed to be applied fast and one-handed. With sturdy materials to be able to exert enough pressure		

reviews and meta-analysis (PRISMA)-statement (www.prisma-statement.org). The search was performed, in collaboration with a medical librarian, in the bibliographic databases PubMed, EMBASE.com and the Cochrane Library (via Wiley) from inception to May 5 2018. The following terms were used (including synonyms and closely related words) as index terms or free-text terms: ‘tourniquet’ and ‘improvised’ and ‘exsanguination’. The references of the identified articles were searched for relevant publications. All search results were entered into and managed with Covidence, an online tool for managing search results for any systematic review (www.covidence.org). Duplicate articles were excluded. The full search strategies for all databases are shown in Appendix A: Supplementary material.

Inclusion criteria

All studies concerning TQs with an improvised design were included into the study. All types of study were accepted; human (civilian and military), animal, cadaver, manikin models. There were no restrictions on publication date or language.

Exclusion criteria

The only exclusion criteria were review studies, exempts from textbooks or studies on TQ-use during elective (orthopedic) procedures.

Risk of bias

Studies were assessed for risk of bias using the tool proposed by the Cochrane Bias Methods Group, the risk of bias in non-randomized studies (ROBINS-1) tool [14]. This tool was developed to assess risk of bias of non-randomized studies for a systematic review. The tool assesses on seven domains of bias (Confounding, Selection, Classification, Deviation from intended intervention, Missing data, Measurement and Publication). These domains assess bias on study and outcome level. As this tool is not intended for case reports and case series, the case reports included in this study were assessed using the tool proposed by Murad et al. in the *British Medical Journal*, Evidence Based Medicine [15]. This tool combines several established assessment tools into eight items that assess four domains of methodological quality (selection, ascertainment, causality and reporting).

Outcome parameters

Efficacy in the simulated environment is measured by either elimination of palpable pulse distal to the TQ, elimination of Echo-Doppler signal distal to the TQ or by the elimination of simulated blood loss in a mannequin leg. Efficacy in the real-life environment is measured by reported cessation of active exsanguination of the wound.

Secondary end points are adverse events such as: amputation, compartment syndrome and nerve palsy. In the simulated environment secondary endpoints were: reported pain, observed impingement of the skin and subjective numbness.

Statistics

Due to expected substantial heterogeneity in study design and study population, we refrained to pool the retrieved data or perform statistical analysis. All reported statistical analysis was performed by the original authors and merely summarized in our manuscript.

Results

Results of the search

The search of the online databases yielded 3563 records and 232 duplicates were identified. A total of 3331 unique studies entered the selection process. These articles were screened on title and abstract by two independent reviewers (MC and AB). Any conflicts were resolved by discussion amongst the reviewers. 3177 studies were deemed irrelevant. The remaining 154 studies were assessed by full-text analysis independently by two reviewers (MC and AB) for eligibility. Conflicts were, again, resolved by discussion, and/or consulting other authors (SvO, LG). Thereafter, 99 studies were excluded because they reported on commercial TQs only. Thirty-four studies met the exclusion criteria. No studies were excluded because of high risk of bias (Fig. 1). All but one study were estimated to have a Moderate risk of bias (“The study appears to provide sound evidence for a non-randomized study but cannot be considered comparable to a well-performed randomized trial”). For a summary of the risk of bias in all studies, see Table 2. All case reports were deemed of adequate methodological quality, although in some cases an alternative cause was not properly ruled out which put the causality conclusion at risk of bias. Twenty studies were included. Data extraction was done by two reviewers (MC and AB) All data regarding I-TQs was extracted. Due to the heterogeneity of the data

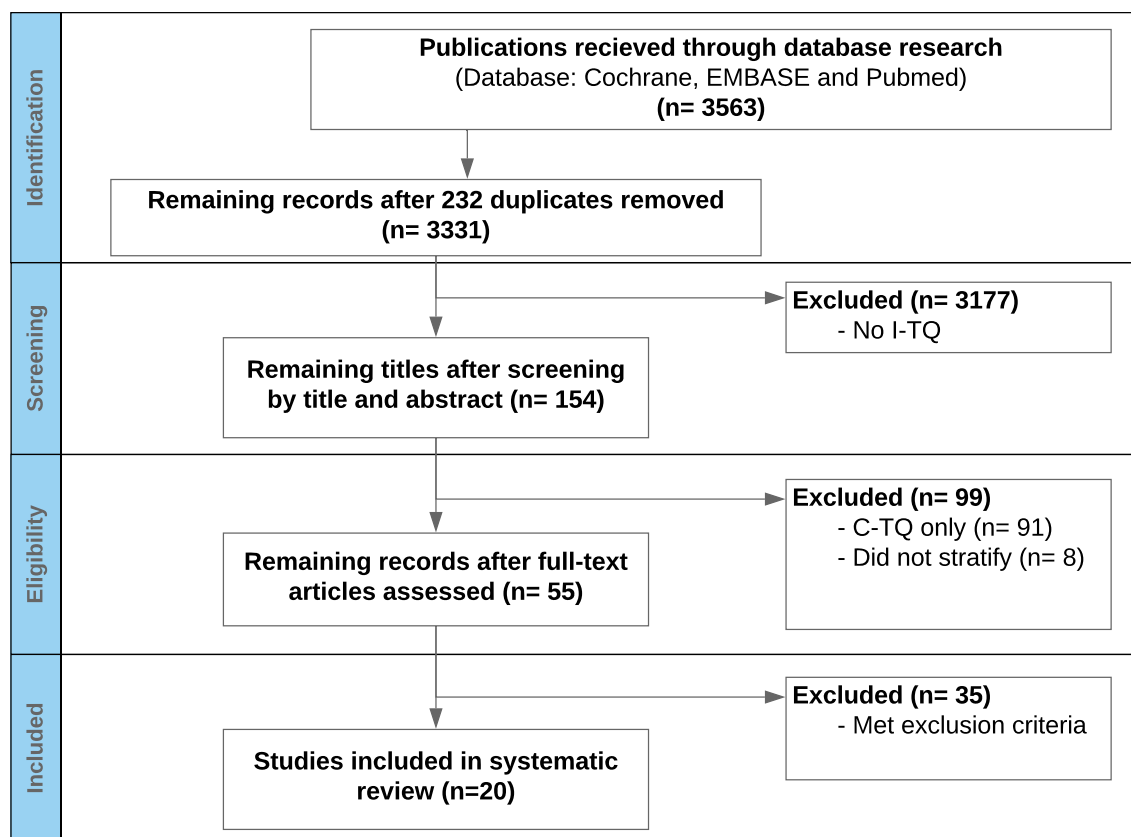


Fig. 1 Flowchart for the selection of studies

Table 2 Results of bias assessment

Author, year of publ	ROBINS-1 risk of bias	Domains of bias at risk
King (2006)	Moderate	Measurement, selection
Swan (2008)	Moderate	Measurement, selection
Guo (2011)	Moderate	Measurement, selection
Heldenberg (2015)	Moderate	Measurement, selection
Altamirano (2015)	Moderate	Measurement, selection
Kragh (2015)	Moderate	Measurement, selection
Lyles (2015)	Moderate	Measurement, selection
Kragh (2008)	Moderate	Measurement, selection
Inaba (2015)	Moderate	Confounding, measurement
Lakstein (2002)	Moderate	Confounding, measurement
Larsen (2004)	Serious	Confounding, deviation, measurement
Zietlow (2011)	Moderate	Confounding, measurement
King (2012)	Moderate	Confounding, measurement
King (2015)	Moderate	Confounding, measurement
Kue (2015)	Moderate	Confounding, measurement
Passos (2014)	Moderate	Confounding, measurement
Schroll (2015)	Moderate	Confounding, measurement
Malo (2015)	Case report	Causality
Dayan (2017)	Case report	Causality
Kragh (2007)	Case report	Causality

no standardized form was made to prevent excluding data. These were categorized into studies reporting experimental studies (Table 3) and clinical use (Table 4). Subgroups were made regarding efficacy and safety and simulated vs real-life situations.

Efficacy

I-TQ Versus C-TQ in a Simulated Environment

King et al. [16] tested several C-TQs and I-TQs on volunteers. The best improvised design was silicone (also called “surgical”) tubing which eliminated a palpable pulse in 100%, and arterial Doppler signal in 90% of applications, thereby outperforming the cloth and wooden dowel design (respectively, 80% and 50%). Of the commercially designed devices the Pneumatic Emergency Medical Tourniquet performed best, eliminating pulse and Doppler signal in 80% of all applications. A statistical comparison between aforementioned designs showed a significant difference for I-TQ vs. C-TQ ($p=0.01$) and I-TQ vs. I-TQ ($p=0.01$). Lyles et al. [17] compared the Combat Application Tourniquet (CAT) to a bandage with eight chopsticks taped together acting as a wooden dowel and a bandana with a similar chopstick wooden dowel applied to a mannequin leg with simulated

blood loss. The CAT outperformed both of the I-TQs significantly ($p=0.0001$). The difference between the bandana and the bandage was not significant ($p=0.50$) [16, 17]. Three studies tested both improvised and commercial designs but made no statistical comparison [8, 18, 19]. I-TQs had success rates ranging from 45 to 90% depending on location and design. The cloth and wooden dowel performed consistently best. The C-TQs success rates ranged from 78 to 100%. Another two studies only tested I-TQs [20, 21] which had similar success rates to previous studies: 42–100%

I-TQ in real-life situations

Thirteen studies described I-TQs in real-life situations [9–11, 13, 22–30]. Most studies did not report on success percentages or the designs used. Kue et al. [11] reported a success rate of 91% for surgical tubing. In contrast, King et al. [10] reported that most surgical tubing I-TQs used by the Boston EMS failed but unfortunately did not include percentages. The cloth and wooden dowel design reached success percentages of 42–100% with multiple cases of success over prolonged periods. Other designs such as belts, wires and cloths with no dowel were either completely unsuccessful or reached up to 25% success rate. Two studies did not report on the efficacy [28, 29].

Table 3 Simulated environment studies on improvised tourniquets

Author, Year of publication	Experimental design	Number of applications	Design, success rate.				Reported complication rate	Type of complication	
King, R.B. 2006	Volunteers	160	Cloth with wooden dowel	Pulse palpation success				Unknown	Highest subjective pain score, skin pinching observed
				Ideal 14/20 (70%)		TQ over winter clothing 16/20 (80%)			
				Echo Doppler success					
				Ideal 6/20 (30%)		TQ over winter clothing 10/20 (50%)			
			Surgical tubing	Pulse palpation success				Unknown	Second highest subjective pain score
				Ideal 20/20 (100%)		TQ over winter clothing 18/20 (90%)			
Swan, K.G. 2008	Volunteers	80		Upper Arm	Upper Leg	Lower Arm	Lower Leg	1/80 (0.01%)	Pain
			Rubber tubing	10/10(100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)		
			Cloth with wooden stick	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)		
Guo, J.Y. 2011	Volunteers	80	Surgical tubing wrapped around extremity tightly		Canvas belt		Unknown	Highest subjective pain score	
			Upper extremity 12/20 (60%) Lower extremity 15/20 (75%)		Upper extremity 9/20 (45%) Lower extremity 12/20 (60%)				
Heldenberg, E. 2015	Volunteers	46	Improvised Russian tourniquet; triangular bandage, wooden dowel.				Unknown	Unknown	
Altamirano, M.P. 2015	Mannequin with simulated blood loss	160	T-Shirt with 6 chopsticks taped together turned 180 degrees		No windlass		Unknown	Swirling of mannequin skin indicating shearing stress	
			54/80 (68%)		1/80(1%)				
Kragh, J.F. jr. 2015	Mannequin with simulated blood loss	360		1 Stick	2 Sticks	3 Sticks	4 Sticks	111/249 (45%)	Breakage of windlass (most contributed by single craft stick)
			Chop stick	17/40 42%	40/40 (100%)	-	-		
			Pencil	21/40 (52%)	37/40 (92%)	33/40(82%)	20/20(100%)		
			Craft stick	0/40 (0%)	24/40 (60%)	38/40 (95%)	20/20 (100%)		
Lyles, W.I. III 2015	Mannequin with simulated blood loss	40	Triangular bandage		Bandana		0/60 (0%)	Usual wear and tear on silicone skin observed	
			8/20 (40%)		2/20 (10%)				

Table 4 Real-life studies on improvised tourniquets

Author name, pub year	Type of study	Trauma mechanism	Number of applications	Design, success rate		Reported Complication rate	Complications
Kragh, J.F. 2008	PA	Explosive device, gun, burn, motor vehicle crash,	16	Cloth and wooden dowel	String, iv tube	12/16 (80%)	Amputation and fasciotomy most common
				3/7(42%) of limbs	2/8 (25%) of limbs		
Inaba, K. 2015	RA	Stab wound 51.7%, Industrial accident	7	No design mentioned 7/7 (100%)		0/7 (0%)	None
Lakstein, D. 2002	RA	Penetrating trauma, mainly caused by explosions	21	Wide rubber band wrapped around limb	Improvised tourniquet, (2 belts, 1 wire)	7/110 (6%)	Nerve palsy
				13/18 (72%)	2/3 (66%)		
Larsen, J.2004	RA	Mine explosions	18	String, belts and cloths 0/18 (0%)		3/18 (17%)	Death
Zietlow, J.M. 2011	RA	Blunt (37%) Laceration (29%) Stab wound (10%) Hemodialysis (7%) Fall 4% Gunshot (4%) Other (10%)	3	Belt 0/3 (0%)		0/3 (0%)	None
King D.R. 2012	RA	Explosive device, gunshot, crush	2	Cloth and wooden dowel. 0/2 (0%)		Not mentioned	Not mentioned
King, D.R. 2015	RA	Improvised explosive device	27	27 improvised tourniquets. Most encountered was surgical tubing wrapped tightly and then twisted with a clamp. Although no numbers mentioned; most were ineffective (venous) tourniquets		Not mentioned	Not mentioned
Kue, R.C. 2015	RA	Penetrating 67%, Non traumatic bleeding 23.5% blunt 9.2%	98	Surgical tubing wrapped around limb, twisted with a clamp	Belts	0/98 (0%)	None
				87/95 (91%)	0/3 (0%)		
Passos, E. 2014	RA	2 penetrating trauma 2 blunt trauma	4	Neck tie, belt, handkerchief. No effectiveness described		0/4 (0%)	None
Schroll, R. 2015	RA	Gunshot (14.7%), Stab (41.6%), Blunt (36%), Unknown (7.5%)	40	40/197 improvised. Design not described, Hemorrhage control percentage not described.		Damage all similar to commercial devices	Amputation, nerve palsy, ischemia/reperfusion
Malo, C 2015	CR	Penetrating trauma by gunshot wound	2	Belt and Seatbelt combined 1/1 (100%)		1/1 (100%)	Tourniquets in place for 17 hours, above the knee amputation.
Dayan, L. 2017	CR	Improvised explosive device creating a traumatic amputation below the knee	1	Cloth with wooden dowel. In place for 11 hours 1/1 (100%)		1/1 (100%)	Above the knee amputation, skin below tourniquet not viable to serve as a flap.
Kragh, J.F. 2007	CR	Gunshot, shrapnel.	2	Wide strap with spring clip.	Cloth with wooden dowel	0/1 (0%)	none
				0/1 (0%)	1/1 (100%)		

PA prospective analysis, RA retrospective analysis, CR case report

Safety

Several studies found complications after TQ use. Three studies have described amputations as a complication [13, 29, 30]. In the case study of Malo et al. [13] an I-TQ remained 17 h in place. This led to an above the knee amputation. The I-TQ used in the case study by Dayan et al. [30] was applied for 11 h after a traumatic below the knee amputation due to an explosive device. After removal of the tourniquet the skin below the level of the TQ position was not viable to serve a flap and an above knee amputation had to be performed. Schroll et al. [29] mentioned a 18.3% amputation rate among the victims, but did not report whether any of the amputations were caused by I-TQs or due to the extent of injury. Lakstein et al. [24] reported nerve palsy after the use of belts, wires and cloth and wooden dowel TQs. Nerve palsies have been reported by Schroll et al. [29] as well. Guo et al. [8] mentioned that a canvas belt had the highest subjective numbness score, compared to an improvised design of surgical tubing tightly wrapped around an extremity. In the experimental studies, pain was

frequently reported as being the worst in the improvised designs compared to commercial designs [8, 16, 19].

Altamirano et al. [20] tested a t-shirt with six chopsticks taped together as a TQ on a manikin model. This led to forceful shearing of the skin. This has been found on a silicone skin in the study of Lyles et al. as well [17].

Discussion

This review found mostly manikin, pre-clinical trials with volunteers and retrospective analyses on I-TQs with large inter-study variability in TQ design, outcome parameters and study population providing solely low-quality evidence (C-level, GRADE Working Group). Because of this level of evidence, no ideal design of an improvised tourniquet regarding efficacy and safety can be pointed out based on the retrieved evidence. Sources of bias such as the inability to differentiate primary injury effect and side effect of treatment make it impossible to draw any statistical conclusions. Also, having not used any standardized forms for data

extraction added a risk publication bias. However, we shall discuss several patterns that emerged from our summary.

Performance of I-TQ's

I-TQs reported in the retrieved studies seem unable to reliably achieve hemorrhage control as all studies comparing commercial devices to improvised designs showed the improvised design to be inferior regarding efficacy. The only studies that showed reliable success rates were either observational studies which took place on healthy subjects in optimal application circumstances or case reports with very small population numbers ($N=1-3$).

A perfect TQ has the ability to completely occlude arterial flow in the affected limb whilst causing the least adverse events such as unbearable pain, nerve palsy or tissue damage. The potential life-saving effect of a TQ must outweigh the risk of adverse events. A good example of an offset balance was shown in the study of Larsen et al. where a North Atlantic Treaty Organization (NATO) operation to clear mines resulted in multiple wounded soldiers, no C-TQs were present and many of the injured had an I-TQ applied by a fellow soldier. A general order to stop using TQs was given after several cases of adverse events linked to TQ use happened [25].

Safety issues

When TQs are unable to stop the arterial flow to a limb due to the inability to achieve sufficient circumferential pressure, a TQ will be ineffective and results in ongoing blood loss. In addition, when the applied pressure of the TQ is high enough to provide venous occlusion but it is too low to achieve arterial occlusion, blood will continue to flow into the injured limb and it will be trapped because of occlusion of the venous outflow (a venous TQ). This results in increasing pressure in the injured limb, which can lead to complications such as a paradoxical increase in bleeding or compartment syndrome [16]. As discussed earlier, most I-TQs were not as effective as C-TQs, which theoretically could result in increased incidence of paradoxical bleeding when using an I-TQ. Also, impingement of the silicone skin under the I-TQ has been reported by several authors [16, 17, 20]. Guo et al. [8] and Swan et al. [19] reported a higher pain score in I-TQs when compared to C-TQs. Although pain may be of minor relevance when a patient is bleeding to death (life over limb), we speculate that lay persons could be withheld to tighten the improvised design appropriately due to increased pain indicated by the victim, thereby adding to the risk of creating a venous, rather than an arterial TQ. Moreover, several studies stated that I-TQ designs generally used had small contact surface areas and sharp

edges, therefore causing severe pain and an increased risk of injury to underlying structures resulting in neuropraxia [31] or tissue damage as reported by several studies [13, 29, 30]. In the case reports the loss of tissue was thought to be linked to the TQ use, but no discretion could be made between primary injury effect and side effect of treatment. In the real-life environment studies, no increased amputation rate is described.

Although the added risk of these complications theoretically seem probable, the retrieved studies have not reported an increase in prevalence of morbidity and mortality when I-TQs were used [9, 11, 23]. However, due to the design of these studies, which were rather small case series. And the difficulty to discriminate whether an adverse event was caused by the trauma itself or by treatment with an improvised tourniquet. No conclusion can be drawn on the possible added risk of adverse events when using an I-TQ vs. C-TQ.

Best design

In order to occlude arterial blood flow, it is essential that the applied pressure of the TQ is sufficient. Of the various improvised designs in the reviewed studies, one design achieved the most consistent occlusion of arterial flow success rates across all studies, which came close to the success rates of C-TQ's. That design consistently included a band and windlass [19–22, 30]. When directly compared to similar designs without a windlass, I-TQ consistently showed very low success rates [8, 20, 24]. Therefore, it appears that the windlass could be a key-element to reach sufficient pressure to occlude arterial flow.

An adequately effective and safe I-TQ design has not been found yet. Moreover, the question whether there is place for the use of such an I-TQ design by bystanders in prehospital care remains to be answered.

Various guidelines have addressed the issue: the American College of Surgeons Committee guidelines advise the use of I-TQ's only when C-TQ's are not available but make no recommendations for the design [32]. The Journal of American Medical Associates advises to apply direct pressure for 15 min, if direct pressure does not stop the bleed they advise a band and windlass design [33]. The American College of Surgeons Bleeding Control program advises to apply direct pressure when there is no C-TQ available [34]. The TCCC recommendations only concern C-TQ's as all soldiers carry a C-TQ with them in their standard pack.

Conclusion

This review reveals little evidence is available concerning several key components: The optimal design of an improvised tourniquet, whether an I-TQ has a higher complication

rate compared to a C-TQ and whether, when laypersons are trained in applying the optimal design, an I-TQ can serve as a reliable option in pre-hospital hemorrhage control. The existing reports do not support the use of improvised designs due to low efficacy and safety concerns. However, from a theoretical perspective, a proper design of an improvised tourniquet applied correctly can save lives.

Therefore, we suggest future studies that focus on finding an optimal effective design which is made with materials that will have a high likelihood of being available on accident scenes and is easily applied. Furthermore, studies are needed that educate the bystanders in properly applying this improvised tourniquet and testing the effectiveness of said education afterwards, possibly in real-life situations.

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Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest.

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