A multi-institutional study of hemostatic gauze and tourniquets in rural civilian trauma

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BACKGROUND: Life-threatening hemorrhage is a leading cause of preventable mortality in trauma patients. Since publication of the Hartford Consensus statement, there has been intense interest in civilian use of commercial hemostatic gauze and tourniquets. Although the military has studied their use on soldiers with wartime injuries, there are limited data on patient outcomes following civilian prehospital use and no data on the use in rural trauma.

METHODS: We performed a multi-institutional retrospective analysis of clinical outcomes following prehospital use of QuikClot combat gauze (QC) and combat application tourniquets (CATs) from 2009 to 2014. The primary outcome measured was effectiveness. Secondary outcomes included morbidity, mortality, patients' demographics, injury characteristics, and hospital outcomes.

RESULTS: Between 2009 and 2014, 95 patients were managed by prehospital personnel with QC and/or CAT. Forty received QC, 61 received CAT, and 6 received both products. The median age was 40 years (6–91 years), 29% were female, and the median injury severity score was 7 (1–25). QuikClot combat gauze was 89% effective. Minimal morbidity was associated with QC use. Combat application tourniquet was 98% effective. Median tourniquet time was 21 minutes (6–142 minutes), the median injury severity score was 9 (1–50), and mortality was 9.8%. Morbidities observed with tourniquet use included amputation, fasciotomy, rhabdomyolysis, and acute kidney injury. Risk of amputation was associated with higher injury severity ($p = 0.04$) but not with elderly age, obesity, or the presence of medical comorbidities. No amputations resulted solely from the use of tourniquets.

CONCLUSIONS: QuikClot combat gauze and CAT are safe and effective adjuncts for hemorrhage control in the rural civilian trauma across a wide range of injury patterns. In a rural civilian population including women, children, and elderly patients with medical comorbidities, these devices are associated with minimal morbidity beyond that of the original injury. (*J Trauma Acute Care Surg.* 2016;81: 441–444. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic study, level V.

KEY WORDS: Tourniquet; hemostatic gauze; external hemorrhage.

Uncontrolled hemorrhage is the leading cause of preventable mortality in injured patients.[1,2] In the recent and ongoing conflicts in Iraq and Afghanistan, the US Military demonstrated the effectiveness and safety of topical hemostatic gauze and commercially available tourniquets for rapid control of hemorrhage in wounded soldiers.[2,3] Based on these studies, the US Military developed the Tactical Combat Casualty Care course, the implementation of which has been associated with decreased mortality due to external hemorrhage.[4] Civilian interest in these products is also growing. Following recent high-profile active shooter events, the Hartford Consensus Group issued a call to action advocating the use of tourniquets and hemostatic gauze by law enforcement and other civilian first responders for expeditious prehospital hemorrhage control.[1]

Two of these products are have been used by all of our prehospital care teams since 2009. QuikClot (QC), manufactured by ZMedica (Wallingford, CT) is a commercially available hemostatic agent composed of sterile gauze impregnated with kaolin, an inert mineral that stimulates the clotting cascade by activation factor XII and platelet-associated factor XI. The Combat Application Tourniquet (CAT) is a commercial tourniquet manufactured by Composite Resources (Rock Hill, SC) that is designed for one-handed application and has a wide strap for arterial occlusion with lower pressure application. This tourniquet was tested in previous military studies and showed effective hemorrhage control with minimal morbidity.[2]

The military data on use of these devices is compelling. Studies of commercial tourniquet use during the war in Iraq and Afghanistan show an association with survival especially for those who received tourniquets in the prehospital setting before the onset of shock.[3] Tourniquets were 79% 92% effective, with minimal morbidity directly related to tourniquet use.[2] Data on the use of hemostatic gauze is less robust. These reports show an 80% to 90% effectiveness for hemorrhage control with greater effectiveness before massive hemodilution and the onset of trauma-associated coagulopathy.[5,6] None of these studies, however, report hospital outcomes or morbidity following the use of hemostatic gauze.

It is not known how these military data will translate to a civilian population with different injury patterns, and a markedly different patient population including female, pediatric, and elderly patients with medical comorbidities. Therefore, we hypothesized that civilian use of hemostatic gauze and commercial

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TABLE 1. Demographic, Physiologic, and Treatment Data of Civilian Patients Treated with CAT or QuikClot

	Overall	CAT	QuikClot
Number of patients	95	61	40
Female, %	29	21	37
Age (median), years	40 (6–91)	35 (6–83)	51 (18–91)
Pediatric, %	4	8	0
Elderly, %	20	12	27
BMI	29 (16.6–45)	28 (18–43)	30 (16.6–45)
Comorbidities, %	42	43	58
Hypotension/Shock, %	26	21	30
Transfusion, %	31	29	32
RBC, mean, units	5.7	7.4	2.5
FFP, mean, units	3.5	4.2	3.4
Platelet, mean, units	0.9	1.0	0.7
Operative management, %	64	67	51
ICU, %	31	27	35
Mortality, %	5	9.8	0

tourniquets would be an effective intervention for hemorrhage control without major morbidity. This work represents the largest rural experience with these products in the civilian literature to date and is the only rural multi-institutional study to fully characterize the safety, efficacy, and morbidity associated with their use in civilian trauma.

METHODS

We conducted a retrospective study of patients who received QC or CAT as treatment of hemorrhage in the prehospital setting from 2009 to 2014. A centralized medical transport service delivered patients to one of 10 participating institutions across the states of Minnesota and Wisconsin. The catchment area for all included hospitals was predominately rural. Prehospital care providers underwent training and certification before use of the devices. All of the devices were applied per strict protocol after failure of direct pressure to achieve hemostasis. This protocol mandated that tourniquets be applied until occlusion of distal arterial pulse was achieved. The prehospital protocol was similar to that proposed by Bulger et al.[7] If direct pressure failed to control hemorrhage or direct pressure was impractical and the injury was on an extremity amenable to a tourniquet, a tourniquet was placed. If the injury was not amenable to tourniquet placement, QC was used. Device effectiveness was defined as cessation of visible hemorrhage and was documented by prehospital providers.

Institutional review board approval was granted at each participating institution. Clinical outcomes were identified by review of patient charts. Variables measured included patients' demographics, injury characteristics, treatment characteristics, and morbidities. Owing to the nature of the injuries for which these products are used, it was not possible to ascertain whether morbidities were the result of the injuries or the devices. Therefore, all-cause morbidity was measured and defined as the sum of traumatic injuries, procedures, and complications.

RESULTS

Ninety-five patients were treated at 10 institutions across the states of Minnesota and Wisconsin. Forty were treated with QC, 61 were treated with CAT, and five patients with multiple injuries required use of both devices to separate injuries. One patient was treated contrary to our protocol with QC initially, which was ineffective, and subsequently had a tourniquet placed to achieve hemorrhage control. The median age was 40.5 years; 29% were female, 20% were elderly (older than 65 years), 4% were of pediatric (younger than 18 years), and 42% had preexisting medical conditions. One quarter of patients presented in hypovolemic shock, 31% required intensive care unit care, and 64% underwent operative intervention for hemorrhage control. The median follow-up was 78 days (Table 1).

QuikClot combat gauze was effective in 89% of cases. The median Abbreviated Injury Severity (AIS) score and the Injury Severity score of this group were 2 (1–5) and 7 (1–50), respectively. Most of the QC was used for wounds on the head or face, 20% was used on the upper extremity, 15% was used on the lower extremity, and three devices were used for junctional hemorrhage. The predominant mechanism of injury was blunt (47%), although a significant proportion of these devices were used for penetrating injuries (37%) and 15% were used for bleeding secondary to medical causes or dialysis access sites (Table 2). There were no mortalities in this group. As a whole, 12.5% of patients who received QC experienced one or more morbidities. One patient had acute kidney injury secondary to hypovolemia, and four patients had superficial infections (Tables 3–4).

Combat application tourniquet was effective in all but one case (98%). In this case, a second tourniquet was added proximally, and hemorrhage control was achieved. Tourniquet use was distributed evenly among upper and lower extremities (52% upper extremity, 48% lower extremity). The predominate mechanism of injury in our study patients was blunt (51%). Thirty-eight percent had penetrating injuries, and six patients had medical causes of bleeding or hemorrhage from dialysis access sites (Table 2). Median tourniquet time was 21 minutes (4–142 minutes). The median AIS was 3 (1–4) and the median

TABLE 2. Injury Characteristics for Patients Treated with CAT and QuikClot

	CAT	QuikClot
AIS (median)	3 (1–4)	2 (1–5)
ISS (median)	9 (1–50)	7 (1–50)
Location, %		
Upper extremity	52	20
Lower extremity	48	15
Chest/Abdomen	–	10
Junctional	–	7.5
Head/Face/Neck	–	47.5
Mechanism, %		
Blunt	51	47.5
Penetrating	38	37.5
Medical/Dialysis complications	10	15

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TABLE 3. Effectiveness and Overall Morbidity for CAT and QuikClot in Rural Civilian Trauma

	CAT	QuikClot
Effectiveness, %	98	89
Device time, median, min	21 (4–142)	30 (3–130)
Overall morbidity, %	18	12.5

injury severity score was 9 (1–50), reflecting the fact that most of the patients had isolated limb injuries. Six deaths occurred in this group. Overall, 18% of patients had one or more morbidities (Table 4). Morbidities documented in patients with CAT use were amputations,[7] fasciotomies,[4] infection,[4] rhabdomyolysis,[1] and acute kidney injury.[1] All patients with major morbidities had a limb AIS of 3 or greater, with the exception of one patient with an AIS of 2 who underwent prophylactic fasciotomies (Table 4). Seven patients sustained amputations in this study. Two were traumatic amputations, and one amputation was due to uncontrollable hemorrhage from a severe lower extremity crush injury. None of the four remaining amputations were unexpected given the nature of the injuries sustained and upon clinical review could not be directly attributed to tourniquet use. Compared to patients with an AIS of 1 to 2, patients with an AIS of 3 to 4 had a significantly higher likelihood of requiring an amputation ($\chi^2 = 4.95$, $p = 0.04$).

Overall, 11% of devices were used for nontraumatic indications including dialysis fistula rupture, bleeding related to arteriovenous malformations, and advanced malignancies. Patients with nontraumatic bleeding were older (median age, 69 years) and had more medical comorbidities. Forty-five percent were receiving therapeutic anticoagulation and 36% received transfusions. Five of the nontraumatic uses were tourniquets placed for bleeding complications of dialysis fistulas, and the only prehospital death occurred secondary to a fistula bleed. All fistulas in patients who survived were functional following tourniquet use.

DISCUSSION

These results fill key knowledge gaps about the prehospital use of hemostatic gauze and tourniquets in the rural civilian setting. First, we show that QC and CAT provide effective hemorrhage control in a rural civilian population, which included elderly, female, and pediatric patients with a wide range of body mass indexes (BMIs) and in the presence of multiple medical comorbidities.

Next, we analyzed the causes of hemorrhage requiring the use of these devices in rural civilian trauma. Civilian trauma clearly is not the same as military trauma. While 91% of patients with tourniquets in the military studies had penetrating or blast injuries, in our cohort, injuries were predominately due to a blunt mechanism, with most of these being motor vehicle crashes causing extensive soft tissue and bone damage. Additionally, we found that in the civilian setting, these products have uses beyond traumatic injury. Overall, 11% of devices were used for hemorrhage from nontraumatic sources including dialysis fistula rupture, bleeding related to arteriovenous malformations, and advanced malignancies. Although the number of patients with dialysis fistulas who received tourniquets was small and limits the generalizability of this finding, this is the first report of outcomes following tourniquet use for dialysis access bleeding. We show that the use of a tourniquet does not universally render dialysis access nonfunctional and suggests that the direct morbidity of tourniquet use for this purpose may actually be negligible. Given the potentially life-threatening nature of dialysis access bleeding, this finding warrants further study.

Morbidity seen with the use of these products was low and could be related to the original injury. Only minor morbidity was seen in patients who were treated with QC. These were mostly superficial wound infections at a rate consistent with that expected for contaminated traumatic injuries.[8,9] Use of CAT was associated with higher injury severity and all-cause morbidity. All major morbidities observed in the study were seen in patients with severe injuries, and the rate observed in this study compares favorably with those reported for severe civilian trauma and in large military tourniquet trials (Table 4). [2] Examination of patients' characteristics showed no significant association between the risk of amputation following tourniquet application with elderly age (older than 65 years), presence of medical comorbidities, or obesity (BMI >25 kg/m^2). In contrast, high AIS was significantly associated with amputation risk in our study population, suggesting that injury severity, rather than patients' characteristics, contributes most to the morbidity associated with injuries requiring tourniquet use.

Tourniquet use in the civilian setting has been criticized for a variety of reasons.[10] One reason commonly cited is that owing to short transport times, the possible morbidity of tourniquets is not a necessary risk in the civilian setting. It has been reported that even in an urban trauma system with short transport times, exsanguination from extremity trauma is still an important preventable cause of death.[11] In rural trauma, transport times can be prolonged and make the need for these adjuncts even greater. In our study, we found no additional morbidity

TABLE 4. Relative Morbidities

	Mayo Civilian		Military
	QuikClot (n = 40)	Tourniquet (n = 61)	Tourniquet Only*
ISS, median	7	9	10
Major morbidity, %	2.4	11.7	NA
Amputation	0	11.5	38
Fasciotomy	0	6.5	28
Rhabdomyolysis	0	1.6	NA
AKI/ARF	2.4	1.6	0.5
Compartment syndrome	0	0	NA
Minor morbidity, %	10	6.5	NA
Thrombosis/DVT	0	0	4.3
Infection	10	6.5	NA
Nerve palsy	0	0	4.3

*Morbidities have not previously been reported in the literature for QuikClot.

Relative morbidities observed in this study compared with those reported for military tourniquets in place less than 2 hours.[3]

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directly attributable to tourniquets when applied up to 142 minutes, our maximum tourniquet time.

Some patients with minor injuries received tourniquets in our study. Some of these were placed for tactical reasons such as prolonged extraction from a motor vehicle or insecure scene. We found that no patients with minor injuries who had a tourniquet placed experienced major morbidity. Thus, there does not seem to be additional morbidity from placement of a tourniquet on a minor injury in our study population. Given these data, it is our opinion that providers in the field should be given the discretion of placement of these devices, with the knowledge that placement on minor injuries does not confer additional morbidity.

This study is limited by its retrospective nature and sample size. Additionally, although all first responders were trained and tested to place tourniquets until arterial occlusion, we do not have objective data to document that this was achieved in all cases other than the report of the individuals involved. This, combined with the number of patients with minor injuries in the tourniquet arm of the study, could bias the effectiveness rate determined.

CONCLUSION

Our data fill an important knowledge gap in the literature and show that QC and CAT are effective for hemorrhage control in the rural prehospital setting for not only blunt and penetrating trauma but also medical causes of bleeding. These devices were not associated with major morbidity in patients with a wide range of ages, BMI, and with medical comorbidities. These data support the widespread use of these devices in civilian prehospital hemorrhage control.

AUTHORSHIP

J.L, D.M. K.M., S.E. D.J., and S.Z. designed the study. J.L. prepared the manuscript. J.L., J.Z., K.B., K.M., and S.E. collected data. JL, JZ , and KB analyzed the data. J.L., D.J., and S.Z. interpreted the data. D.M., D.J., and S.Z. edited the manuscript. S.Z. conceptualized the study.

DISCLOSURE

The authors declare no conflicts of interest.

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