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A Multi-Institutional Study of Hemostatic Gauze and Tourniquets in Rural Civilian Trauma

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Abstract:

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 is limited data on patient outcomes following civilian pre-hospital 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 (CAT) from 2009-2014. The primary outcome measured was effectiveness. Secondary outcomes included morbidity, mortality, patient 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 CAT, and 6 with both products. The median age was 40 years (6-91), 29% were female, and the median ISS was 7 (1-25). QC was 89% effective. Minimal morbidity was associated with QC use. CAT was 98% effective. Median tourniquet time was 21 minutes (6-142), the median ISS 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: QC 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.

Level of Evidence: Epidemiologic/prognostic study, level III

Key Words: Tourniquet, Hemostatic Gauze, External hemorrhage

Background

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 United States 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 U.S. 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 utilized by all of our prehospital care teams since 2009. Quik Clot (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 80-90% 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 this 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 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 2009-2014. 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 prior to 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 Bulgar 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.

IRB approval was granted at each participating institution. Clinical outcomes were identified by review of patient charts. Variables measured included patient demographics, injury characteristics,

treatment characteristics, and morbidities. Due 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:

95 patients were treated at 10 institutions across the state of MN and WI. Forty were treated with QC, 61 with CAT, 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 (age > 65), 4% were pediatric (age < 18), and 42% had preexisting medical conditions. One quarter of patients presented in hypovolemic shock, 31% required ICU care, and 64% underwent operative intervention for hemorrhage control. The median follow up was 78 days (Table 1).

QC was effective in 89% of cases. The median AIS and ISS of this group was 2 (1-5) and 7 (1-50) respectively. The majority of QC was used for wounds on the head or face, 20% was used on the upper extremity, 15% 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 suffered acute kidney injury secondary to hypovolemia and four patients had superficial infections (Table 3-4).

CAT 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). The median AIS was 3 (1-4) and the median ISS was 9 (1-50) reflecting the fact that the majority of 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 or 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 4 remaining amputations were unexpected given the nature of the injuries sustained and upon clinical review could not be directly attributed to tourniquet use. As compared to patients with an AIS of 1-2, patients with an AIS of 3-4 had a significantly higher likelihood of requiring an amputation (Chi squared = 4.95, p = 0.04).

Overall, 11% of devices were used for non-traumatic indications including dialysis fistula rupture, bleeding related to arteriovenous malformations, and advanced malignancies. Patients with non-traumatic bleeding were older (median age = 69) and had more medical comorbidities. Forty-five percent were receiving therapeutic anticoagulation and 36% received transfusions. Five of the non-traumatic uses were tourniquets placed for bleeding complications of dialysis fistulas, and the only pre-hospital 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 BMI's 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 the majority of these being motor vehicle accidents 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 non-traumatic 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). CAT use 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 (2) (Table 4). Examination of patient characteristics showed no significant association between the risk of amputation following tourniquet application with elderly age (age > 65), presence of medical comorbidities, or obesity (BMI > 25). In contrast, high AIS was significantly associated with amputation risk in our study population suggesting that injury severity, rather than patient 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 due 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 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.

Author Contributions:

Jennifer Leonard: Study design, Manuscript Preparation, Data Collection, Analysis, and Interpretation

John Zietlow: Data Collection, and Analysis

David Morris: Study Design, Manuscript Editing

Kathleen Berns: Data Collection, and Analysis

Kurt Martinson: Study Design, Data Collection

Steven Eyer: Study Design, Data Collection

Donald Jenkins: Study Design, Data Interpretation, Manuscript Editing

Scott Zietlow: Study Conception and Design, Data Interpretation, Manuscript Editing

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Table 1: Demographic, Physiologic, and Treatment Data of Civilian patients treated with CAT or QuikClot

	Overall	**CAT**	**QuikClot**
Number	95	61	40
Female	29%	21%	37%
Median Age (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 (units, mean)	5.7	7.4	2.5
FFP (units, mean)	3.5	4.2	3.4
Platelet (units, mean)	0.9	1.0	0.7
Operative Management	64%	67%	51%
ICU	31%	27%	35%
Mortality	5%	9.8%	0%

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%

CAT – Combat Application Tourniquet, AIS – Abbreviated Injury Severity, ISS – Injury Severity Score

Table 3: Effectiveness and Overall Morbidity for CAT and QuikClot in Rural Civilian Trauma

	CAT	**QuikClot**
Effectiveness (%)	98%	89%
Median Device Time (Min.)	21 (4-142)	30 (3-130)
Overall Morbidity (%)	18%	12.5%

CAT – Combat Application Tourniquet and QuikClot

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%

Table 4: Relative morbidities observed in this study compared with those reported for military tourniquets in place less than 2 hours (3).

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