

Prehospital use of hemostatic dressings by the Israel Defense Forces Medical Corps: A case series of 122 patients

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BACKGROUND:	Hemostatic dressings are advanced topical dressings designed to control hemorrhage by enhancing clot formation. These dressings may be effective when used on injuries sustained in junctional zones. The Israeli Defense Forces Medical Corps (IDF-MC) chose to equip its medical personnel with the QuikClot Combat Gauze. There is a paucity of data describing clinical use and results of hemostatic dressing especially at the point of injury. The purpose of this article was to report the IDF-MC experience with prehospital use of the QuikClot Combat Gauze in junctional zones in a case series retrieved from the IDF Trauma Registry.
METHODS:	All IDF Trauma Registry documented cases of prehospital use of hemostatic dressings in the IDF-MC between January 2009 and September 2014 were retrieved. Data collection included injury mechanism, wound location, reported success of hemostatic dressing, tourniquet use, lifesaving interventions, mortality, and caregiver identity.
RESULTS:	A total of 122 patients on whom 133 hemostatic dressings were applied were identified. Median age was 22 years. Of the patients, 118 (96.7%) were male and 2 (1.6%) were female (missing, n = 2). Injury mechanism was penetrating in 104 (85.2%), blunt in 4 (3.3%), and combined in 14 (11.5%) patients. Seven patients (5.9%) died. Thirty-seven dressings (27.8%) were used for junctional hemorrhage control (pelvis, shoulder, axilla, buttocks, groin, neck), and 92 dressings (72.1%) were placed in nonjunctional areas (missing, n = 4). Nonjunctional dressings included 63 (47.4%) applied to the extremities, 14 (10.5%) to the back, and 4 (3%) to the head. Hemostatic dressing application was reported as successful in 88.6% (31 of 35 available; missing, n = 2) of junctional hemorrhage applications and in 91.9% (57 of 62 available; missing, n = 1) of extremity hemorrhage applications.
CONCLUSION:	Hemostatic dressings seem to be an effective tool for junctional hemorrhage control and should be considered as a second-line treatment for extremity hemorrhage control at the point of injury. (<i>J Trauma Acute Care Surg.</i> 2015;79: S204–S209. Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved.)
LEVEL OF EVIDENCE:	Therapeutic study, level V.
KEY WORDS:	Hemostatic dressing; junctional hemorrhage; extremity hemorrhage; QuikClot Combat Gauze; prehospital care.

Hemorrhage continues to be the leading cause of preventable death on the battlefield,^{1,2} and more effective hemorrhage control at the point of injury (POI) may reduce battlefield mortality and morbidity.³ While massive hemorrhage from extremities may be adequately controlled with tourniquets, control of junctional hemorrhage remains an area of ongoing research as it represents a significant preventable cause of death and poses significant challenges in the field.⁴

Hemostatic dressings have improved hemorrhage control in the battlefield.⁵ They are commonly classified by their mechanism of action: factor concentrators adsorb water from blood and concentrate clotting factors, procoagulants activate the clotting cascade or provide clotting factors, and mucoadhesives

form cross-links between the cellular blood components. Military medical organizations around the globe have been studying hemostatic dressings as early as 1948.⁶ QuikClot Combat Gauze (QCG) is a hemostatic dressing produced by Z-Medica (Wallingford, CT). The product is surgical gauze coated with kaolin, an inert mineral that initiates the coagulation cascade upon contact with injured endothelium via the contact pathway. QCG acts as both a factor concentrator and a procoagulant and has been proven to be safe and to cause minimal local tissue damage and embolization.⁷ It was approved in 2008 by the Committee on Tactical Combat Casualty Care (CoTCCC) to be the first-line treatment for life-threatening hemorrhage for injuries not amenable to tourniquet application⁸ and has also been used in civilian prehospital settings.⁹

All randomized trials to date comparing the different hemostatic dressings have used an animal model. Furthermore, very limited data describing the clinical use of QCG are available in the literature. In December 2013, Gegel et al.¹⁰ performed a comprehensive review of the known literature regarding the use of QCG in porcine and human models. Eight articles on porcine models were identified, with only three articles describing use in humans. The reviewers' conclusion was that while QCG was safe, the evidence did not conclusively demonstrate it to be an effective hemostatic agent for use in trauma patients, although

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preliminary results were promising. We previously described our initial experience with QCG in 14 cases,¹¹ and this remains the largest case series of published prehospital data to date.

Our aim was to describe the current IDF-MC experience with the prehospital use of QCG, especially its effectiveness in junctional trauma hemorrhage control.

PATIENTS AND METHODS

Hemostatic Dressings in the Israeli Defense Forces

The Israeli Defense Forces Medical Corps (IDF-MC) operates in an echelon-based system. The echelons are also referred to as roles, where Role 1 is traditionally the medical care and evacuation means available at the battalion level, while Role 2 capabilities are found at the larger brigade level.¹² In the IDF-MC system, advanced life support (ALS) providers (physicians or paramedics) are placed classically at the Role 1 level. During recent ground operations in the Gaza Strip (Protective Edge and Cast Lead), however, ALS providers were embedded farther forward, with the fighting troops.

QCG is the hemostatic dressing used by the IDF-MC. Our clinical practice guidelines (CPGs) advocate its use as an initial choice for junctional zones (pelvis, shoulder, axilla, buttocks, groin, and neck) and injuries not amenable to tourniquet application such as the back for wound packing.¹³ Application of QCG to the chest and abdomen is not indicated in our CPG because most bleeding in these cavities is not amenable to packing at the POI, and in these cases, rapid evacuation to a medical facility with surgical capabilities is stressed. For extremity wounds, the CPG recommends QCG use if direct pressure (using an "Israeli bandage") or tourniquet application failed.¹¹ All combat soldiers are equipped with the Israeli bandage and the CAT (Combat Application Tourniquet, Composite Resources Inc., Rock Hill, SC), while the QCG is readily available to all medics and ALS providers. The CPGs devised in 2009¹¹ for IDF-MC caregivers regarding QCG use have not undergone any substantial changes since then, and indications and contraindications for use have not been altered throughout the study period.¹³

The IDF Trauma Registry

The IDF Trauma Registry (ITR) is a prehospital military trauma registry containing data on all traumatic casualties (civilian or military) cared for by military medical teams since 1994^{14,15} as part of the Trauma and Combat Medicine Branch (TCMB) in the IDF-MC. Data are collected by medical providers at the POI in the form of casualty cards containing concise data regarding location, mechanism, treatment, casualty status, as well as means and destination of evacuation. These data are subsequently entered into the ITR within a few hours from injury by the treating physician or paramedic. During war scenarios and high-intensity conflicts such as Operation Protective Edge and Operation Cast Lead, these data and additional data gathered by TCMB debriefing teams deployed to the field and to receiving hospitals are entered into the ITR by the TCMB staff. Additional data are available for casualties evacuated by the IDF's Airborne Search and Rescue Unit from their internal event reports and debriefings. Finally, data from the hospital course are collected and entered into the ITR. There is a specific field in the ITR for

capturing whether a hemostatic dressing was used, with a field for perceived success of the dressing in attaining hemorrhage control. Success is based on the caregiver's subjective assessment of complete cessation of the bleeding after application of the QCG with pressure application of 3 minutes. An additional field includes number of dressings used on the wound. Select data fields in the ITR are mandatory, among them caregiver training level (e.g., physician or medic) and several related to medical procedures including the hemostatic dressings (e.g., placement site, success, complications, and tactical setting during the procedure). Although these fields are mandatory, "unknown" is a permitted entry if necessary, resulting in some missing data.

Study Design

The study was conducted as a case series of all documented cases known to be treated with a hemostatic dressing by IDF medical providers in the prehospital setting from January 2009 through September 2014. Subjects were identified by documentation of prehospital hemostatic dressing use in the ITR.

Prehospital data collection included demographic information, injury mechanism, nature and severity of injury, vital signs, Glasgow Coma Scale (GCS) score, lifesaving interventions (LSIs) (defined to include intubation, cricothyroidotomy, needle thoracostomy, and chest tube thoracostomy), as well as concurrent use of intravenous crystalloids, tranexamic acid (TXA) (included in the IDF-MC CPGs since 2011¹⁴) and reconstituted freeze dried plasma (FDP). The last one is the fluid of choice for severe hemorrhagic shock as per the IDF-MC CPGs as of 2013 and is administered by ALS providers.¹⁶ Hospital data included severity of injury, vital signs, select laboratory blood work taken upon hospital arrival, procedures and operations performed, and mortality.

Continuous data are presented as medians and interquartile ranges; categorical data are presented as absolute numbers and percentiles.

This study, involving anonymized data, was reviewed and approved by the IDF-MC's Institutional Review Board.

RESULTS

Patient Characteristics

Between January 2009 and September 2014, 122 patients were identified, on whom 133 hemostatic dressings were applied (median of one dressing per patient). Median age was 22 years (interquartile range, 20–24; missing, n = 4). A total of 118 patients (96.7%) were male, and 2 (1.7%) were female (missing, n = 2). Recorded injury mechanism was penetrating in 104 (85.2%), blunt in 4 (3.3%), and combined in 14 (11.5%) patients. Patient characteristics, vital signs, and additional treatments performed are presented in Table 1.

Circumstances surrounding the injury included routine security missions performed by the IDF (such as reconnaissance missions and dismounted patrols) (n = 31, 25.4%); high-intensity conflicts in the Gaza Strip (n = 71, 58.2%) including Israel's most recent conflict Operation Protective Edge (n = 63, 51.6%); Syrian civilians, victims of the Syrian civil war who reach Israel's northeast border seeking medical assistance (n = 18, 14.8%);¹⁷ and at sea (n = 2, 1.6%). The Syrian patients are included in this series because they are treated by the same

TABLE 1. Demographics, Vital Signs, and Additional Procedures Performed on Study Participants

Demographics and Mechanism	
Age, y	22 (20–24) [118]
Sex, male, n (%)	118 (96.7%) [120]
Mechanism, n (%)	[122]
Penetrating	104 (85.2)
Combined	14 (11.5)
Blunt	4 (3.3)
Initial field measurements	
HR, beats/min	94 (80–118) [84]
Sat, %	97 (82–98) [98]
Prehospital treatment	
LSI \geq 1, n (%)	30 (30.9) [97]
Crystalloids > 500 mL, n (%)	74 (72.5) [102]
Tourniquets, n (%)	45 (50.6) [89]
FDP, n (%)	21 (21.9) [96]
TXA, n (%)	65 (53.3) [122]
Follow-up	
Death n (%)	8 (6.8) [118]

Demographics, vital signs and additional treatments among 122 patients treated with the QCG in the prehospital setting. All values are medians (interquartile range) unless otherwise indicated. The number of casualties available for each analysis is given in brackets.

HR, heart rate; Sat, saturation.

IDF-MC personnel, using the same medical equipment and according to standard IDF-MC CPGs. All Syrian casualties in this report were treated with the QCG within 1 hour of their injury.

ALS providers applied 82.0% of the dressings (109 of 133), and medics applied 5.3% of the dressings (7 of 133); data regarding caregiver training level were missing for 12.8% of the dressings (17 of 133).

Tourniquets were applied concurrently on 45 patients (50.6%; 45 of 89; missing information regarding tourniquet use, 33 patients), of which 17 were applied to the same limb as the hemostatic dressing. Of these latter 17 cases, 8 were documented trials of conversion of a tourniquet to a hemostatic dressing; 5 dressings were placed after documented tourniquet failure (including 3 cases of hemorrhage control failure and 2 cases of tourniquet placement distal to the principal hemorrhaging wound); in the remaining 4 cases, it could not be determined which of the tourniquet or the hemostatic dressing was placed earlier.

Of the patients, 30.9% (30 of 97; missing, $n = 25$) required LSIs; 72.5% of the patients (74 of 102; missing, $n = 20$) received one or more 500-mL boluses of crystalloids, and 21.9% (21 of 96; missing, $n = 26$) were transfused with FDP. Of the patients, 53.3% (65 of 122) were treated with TXA.

In one patient who survived his injury, massive hemorrhage from an upper thigh injury could not be controlled with either a tourniquet or hemostatic dressing packing. Hemorrhage control was finally achieved by internally compressing the injury with a Foley catheter that was inflated inside the wound. In another patient who was severely injured from an improvised explosive device while on foot (who later died of his wounds), a total of five hemostatic dressings were applied, two successfully to the groin bilaterally after distal tourniquet failure and three unsuccessful applications to the buttocks.

Mortality was documented in seven patients (5.9%; 7 of 119; missing, $n = 3$). Four patients were killed in action, while three patients were classified as died of wounds.

Anatomic Site Placement and Success Rate of Hemostatic Dressings

Of 133 dressings, 37 (27.8%) were used for junctional hemorrhage control (pelvis, shoulder, axilla, buttocks, groin, and neck) and 92 (72.1%) were placed in nonjunctional areas (missing, $n = 4$). Among the 92 nonjunctional dressing applications, 63 (68.5%) were applied to the extremities, 14 (15.2%) to the back, 4 (4.3%) to the head, 10 (10.9%) to the chest, and 1 (1.1%) to the abdomen. The last two applications (chest and abdomen) are not consistent with our current clinical guidelines. Hemostatic dressing application was reported as successful in 88.6% (31 of 35; missing, $n = 2$) of the junctional hemorrhage applications and in 91.9% (57 of 62; missing, $n = 1$) of the extremity hemorrhage applications. Data regarding success were missing in a total of seven cases (four unknown placements and three undetermined success for back, neck, and lower extremity) and were not concurrent with CPGs in another 11 cases (application of dressing to the abdomen or chest). Figure 1 displays the reported hemorrhage control success rate by body region.

Medic and ALS provider success rates with hemostatic dressing applications were 80.0% (4 of 5; missing, $n = 2$) and 91.0% (91 of 100; missing, $n = 9$), respectively. Among casualties who underwent at least one LSI, hemostatic dressing application success was seen in 91.3% (21 of 23; missing, $n = 7$) versus 94.8% (55 of 58; missing, $n = 8$) among those who did not undergo any LSI.

DISCUSSION

This case series was composed to describe the IDF-MC experience with prehospital use of hemostatic dressings. Because of the lack of available clinical human data, a case series examining its effectiveness in junctional hemorrhage control was warranted. Hemorrhage control with the hemostatic dressing was reported to be successful in 88.6% of junctional applications and in 91.9% of nonjunctional applications. These results suggest that the QCG is an effective tool for hemorrhage control in both junctional and nonjunctional injuries.

The safety⁷ and efficacy⁸ of QCG have been previously demonstrated in animal models. Johnson et al.¹⁸ studied an animal femoral artery and vein transection model with 30% hemodilution and found QCG to be clinically superior to packing with standard gauze at controlling hemorrhage while also creating a more robust clot. They also found it to be superior in a resuscitation model, as QCG provided greater latitude with fluid resuscitation while producing a clot that could withstand movement without rebleeding.¹⁹ There are limited data demonstrating the effectiveness of QCG in humans. Besides our previous case series of 14 cases,¹¹ King²⁰ reported use of QCG in 2011 at an army combat hospital operating room, and several case reports from the gynecologic and obstetric fields reported similar success.^{21,22} Our current study adds to the body of literature by presenting the largest case series published to date describing prehospital use of QCG on hemorrhage from junctional zones and extremities.

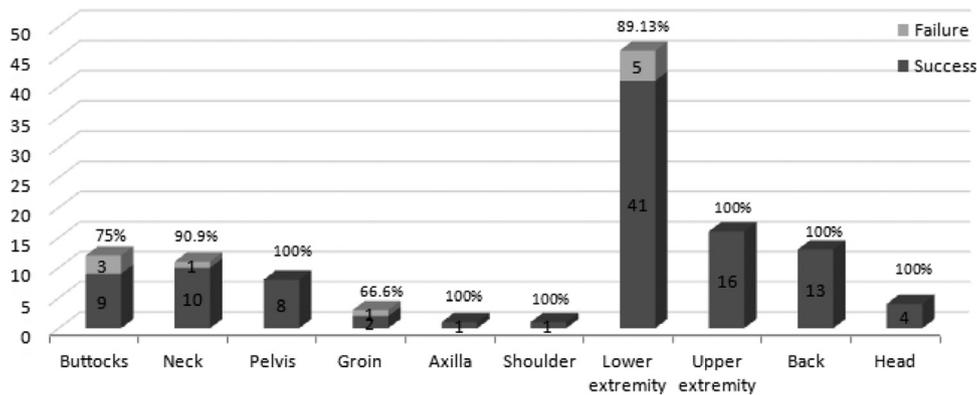


Figure 1. Success versus failure of hemostatic dressing application in different anatomic sites. Data shown for 115 of 133 dressings. Missing anatomic placement (n = 4), undetermined success (n = 3) (back, neck, and lower extremity), and placement not concurrent with CPGs (n = 11) are not displayed. Absolute numbers are shown within the bars, and success percent shown above the bars.

The 88.6% self-reported success rate in junctional hemorrhage control is encouraging, as junctional hemorrhage is increasingly looked at as the currently most common cause of preventable death in the battlefield.²³ Recently, junctional tourniquets have been introduced into the battlefield as another form of junctional hemorrhage control and are the most suitable tool for high amputations and for controlling hemorrhage from large artery lesions.²³ As of October 2014, four models of junctional tourniquets have been developed commercially and cleared by the US Food and Drug Administration. Successful use of the Abdominal Aortic Tourniquet,²⁴ the Combat Ready Clamp,²⁵ and the SAM Junctional Tourniquet²⁶ has already been reported. Widespread fielding and use of such devices have not yet occurred. Currently in the IDF-MC, junctional tourniquets are not available, and the light, portable hemostatic dressings remain a means to control junctional zone hemorrhage by wound packing.

While our CPGs advocate the use of the QCG for packing of junctional hemorrhage not amenable to tourniquet application, our findings might also suggest it to be a valuable tool in the control of extremity hemorrhage. Of note, in five patients, successful dressing application was used after tourniquet failure. In the Operation Protective Edge, 89 CATs were placed because of extremity injuries with a reported 80% success rate, which is comparable with previous data.²⁷ Tourniquets have clear advantages in tactical combat scenarios, mass-casualty events, and self-aid use, and hence should still be the preferred method for controlling extremity hemorrhage given the proper circumstances. QCG may be used in addition to the tourniquet in case it does not completely cease the bleeding or as a second-line of treatment in case of tourniquet failure such as placement of the tourniquet distal to the wound. There were eight cases of successful conversions of tourniquets to QCG dressings during the Operation Protective Edge. Our findings reinforce previous CoTCCC recommendations²⁸ that hemostatic dressings should be the dressing of choice for tourniquet conversion attempts, an important aspect of casualty care in lengthy evacuation routes.²⁹

Most dressings were applied by ALS providers. We attribute this primarily to the fact that in recent ground operations,

ALS providers were embedded within the fighting troops and were thus available to treat casualties within a few minutes of injury; this served to obviate the need for the medic to apply a hemostatic dressing. There was no clear difference in application success rates between medics and ALS providers, most likely because of the very small number of medic applications. It is difficult to draw conclusions from this and apply them in other medical corps as most do not place ALS providers at the POI, and medic training and proficiency vary between armies. The 11 applications of dressings to the chest and abdomen, not in accordance with our CPGs, reinforce the need for continuous medical refresher training. This is especially true during war scenarios, as the medical corps relies heavily on reserve physicians and paramedics.

During the past few years, new chitosan-based hemostatic dressings have become available for use and are reported to be able to stop bleeding independently of wounded coagulation profile status.³⁰ Successful outcomes in animal models³¹ and battlefield uses have been published.^{32,33} Recent publications in punctured femoral artery swine models found QCG and the novel hemostatic dressings such as Celox Gauze (Medtrade Products Ltd., Crewe, United Kingdom) and Chitogauze (HemCon Medical Technologies, Portland, OR) equally effective in terms of arterial hemorrhage control.³⁴ In our opinion, this justifies the recent CoTCCC proposal to add Celox Gauze and Chitogauze to the TCCC Guidelines.²⁸ Further development of novel products designed to control hemorrhage in subjects with trauma-induced coagulopathy in the prehospital setting—including the combat zone—is much needed.

Our study has several limitations. There was no control group, and the caregiver's subjective assessment of hemorrhage control without any means of hemorrhage quantification or vital sign threshold was used to determine the dressing's success. In contrast, perceived success rate by subjective assessment of bleeding control is often used in clinical decision making. The study population consisted of patients with heterogeneous injury severity, thus making it difficult to draw conclusions regarding the dressing's true efficacy in severely injured patients. Moreover, despite an improvement in our prehospital data collection as exemplified in the Operation Protective Edge, studying POI care

has inherent challenges in data acquisition such as POI vital signs and difficulty in information gathering in mass-casualty events. That said, this is the largest series to date to study POI use of hemostatic dressings in human casualties receiving field military care. This study was enabled by having a comprehensive data collection approach, as detailed earlier, coupled with an established prehospital trauma registry.

In conclusion, our case series of 133 QCG applications on 122 patients at the POI demonstrate it to be effective for junctional and nonjunctional hemorrhage. While tourniquet application should be the initial and principal method for extremity hemorrhage control, the QCG may be considered as the initial tool for junctional zone hemorrhage. As junctional tourniquets become more available in the field, further refinement of the CPGs will be required to determine the appropriate roles for the different junctional hemorrhage control tools. Hemostatic dressings should also be considered for wound packing, tourniquet conversion, and tourniquet failure. The importance of prehospital data gathering cannot be overemphasized to scrutinize the dressing's effectiveness in the field.

AUTHORSHIP

The authors have contributed to the manuscript in the following manner: A.S. contributed to the study design and E.G. formulated the concept. A.S. and M.L. contributed to data acquisition. R.N. performed the statistical analysis. A.S., A.M.L., A.B., A.Y., Y.R., and E.G. contributed to data interpretation. All authors participated in manuscript preparation. E.G. contributed to the critical review.

DISCLOSURE

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