

Auto-transfusion tourniquets: the next evolution of tourniquets

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Abstract: In this article, we discuss the relationship between hemorrhagic shock and the pathophysiology of shock using conventional tourniquets. We will focus on corollary benefits with the use of HemaClear[®], a self-contained, sterile, exsanguinating auto-transfusion tourniquet. This discussion will demonstrate that the use of auto-transfusion tourniquets is a practical evidence-based approach in fluid resuscitation: it shortens the duration of shock after hemorrhage and trauma compared with conventional tourniquets. Emphasis is placed on the use of the HemaClear[®] as an alternative fluid resuscitation tool which is more efficient in the battlefield, pre-hospital and in-hospital settings.

Keywords: auto-transfusion tourniquet, field exsanguination, hemorrhagic shock, tourniquet, perfusion requirement, HemaClear[®] ATT

Introduction

Intra-abdominal arterial hemorrhage: a case report and proof of concept

A 73-year-old woman was brought into the Emergency Department (ED) of Eisenhower Medical Centre, Rancho Mirage, CA, USA, after being found unconscious in bed by a relative. She had been complaining of stomach pain for several hours prior. Paramedics found her to be unresponsive with a systolic blood pressure (BP) lower than 40 mmHg, her complexion pale and ashen, and with poorly responsive pupils. They assisted breathing, started intravenous (IV) lines, and transported her to the ED, where she was immediately intubated. Her abdomen was noted to be distended and firm. Fluids were continued after arrival to the ED. After two liters of crystalloid, a dopamine pressor drip was started. She was given two units of O-negative packed red blood cells, followed by three units of typed and cross-matched blood. A computed tomography (CT) with contrast of the abdomen demonstrated massive hemoperitoneum; the contrast blushed in the area of the splenic artery, suggesting a ruptured aneurysm. Thrombocytopenia was noted, and she was given two platelet pack. During this resuscitation, the systolic BP never rose above 60 mmHg.

At that point, the physician elected to try the HemaClear[®] (OHK Medical Devices, Inc, Grandville, MI, USA), a self-contained, sterile, exsanguinating auto-transfusion tourniquet (ATT). After rolling a tourniquet on each leg up to the upper thigh, the systolic pressure increased immediately to 100 mmHg. The dopamine was tapered off and the patient was transferred to interventional radiology, where attempts to coil/thrombose the aneurysm for 2 hours were unsuccessful. At one point, the systolic blood pressure (BP) went up to 140 mmHg. The tourniquets were then rolled down to above the knee;

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this was followed by an immediate drop of systolic blood pressure to 50 mmHg. Therefore, the tourniquets were rolled back up to the previous position, and the systolic BP again rose to 100 mmHg. The patient was then taken to the operating room, where successful splenectomy and ligation of vessels was performed. The total tourniquet time was 4.5 hours on both legs. The patient survived and was discharged from the hospital 5 days later; she had a foot-drop nerve injury in one leg that was likely a complication of the compression.

Although this case report is not a typical combat or battlefield pathology, there is a direct analogy to a penetrating ballistic wound with an arterial bleeder in the abdomen or an edged weapon injury such as a stab wound. It is also important to note that a previously healthy soldier or officer is likely to have greater reserves than a frail 73-year-old female. In our experience, it seems that younger patients do well longer and are able to generate compensatory mechanisms before having an abrupt cardiovascular collapse at the end.

Hemorrhagic shock A time-sensitive problem

When a patient has lost a very large amount of blood volume, there is very little that can be done to save them. One reason is that even two large-bore IV transfusion lines running at maximum flow cannot keep up with rapid blood loss. Secondly, crystalloid volume, which has no oxygen carrying capacity, is replacing the lost blood. Although the fluid replaces intravascular volume, it dilutes the blood and the oxygen-carrying capacity of the blood drops. If the total blood loss approaches 40% of the blood volume, the mortality approaches 100% even when the patient is being treated at a trauma center. Despite replacing the blood loss with packed cells and fluids, further clotting coagulopathies, hypothermia, and acidosis and organ failure of the heart, lungs and kidneys can develop. For the past 10 years, published studies have supported the concept of “permissive hypotension”, which mean avoiding efforts that bring the systolic BP higher than 90–100 mmHg, as a higher blood pressure may encourage bleeding.^{1,2} Thus, avoidance of over-resuscitating the hypovolemic hemorrhaging patient appears to improve survival.

Pathophysiology of shock Perfusion supply and demand: tourniqueting

During the past 10 years, it has been argued that early use of tourniquets on extremities to stop blood loss clearly saves lives and is an important tool to re-emphasize in the

emergency care setting.³ It is recognized that the physiological effect of an appropriately placed tourniquet will stop arterial flow to the extremity; but at a lower pressure, it will stop the venous flow to the extremity and trap the blood in the leg. As a result, clotting occurs, and the blood lactate concentration will rise in the retained blood and will be released into the systemic circulation when the tourniquet is released. In addition, the blood can also be removed from the uninjured leg, thus removing the other leg from the perfusion-demand equation. If necessary, the maneuver can be repeated on the arms. Because a 40% blood volume loss is nearly always fatal as a result of hypoperfusion of vital organs, by removing lower extremity perfusion from the demand side of the equation, the same volume of blood will now adequately perfuse the vital organs.

Review of the literature and ongoing discussions with vascular surgeons suggest that each leg in an adult male can hold up to 500 cc (two units) of whole blood, exactly matched to the patient, with a zero risk of transfusion reactions, containing all the normal clotting factors.^{4,5} If both legs were to be used, the auto-transfusion would equate to one liter of whole matched blood. Secondly, by tourniqueting the legs at the upper thigh, or femoral artery, perfusion demand of approximately 40% of the cardiac output is being removed. This is equivalent to cross-clamping the aorta to preferentially shunt the limited cardiac output to the vital organs. The extremities can be viewed as reservoirs of life-saving whole blood that can be temporarily tapped to keep a patient stable during the time required to get to definitive therapy. Studies in 500,000 orthopedic cases and with normal volunteers have shown there is zero risk involved in this procedure if used less than 2 hours.^{6,7} If the tourniquet time is prolonged, the incidence of compartment syndrome and nerve injuries increases. Alternating legs every 2 hours if both legs are not used at one time would prevent the complications and allow for prolonged use of the device.

Innovation in the field Field exsanguination and HemaClear® ATT

On the battlefield, necessity is the mother of invention. Consideration of what could be done in the field when faced with a hemorrhaging patient or a hemorrhagic shock patient has led to finding innovative ways of extending time to get the patient to definitive care. A variety of tourniquets are currently available for this purpose. It makes sense to elevate the leg before tourniqueting to drain some of the venous blood

into the core circulation. For decades, this procedure has been used in orthopedic surgery.^{8,9} The leg is then elevated for 60 seconds, an Esmarch rubberized dressing placed distally, and wrapped proximally to compress the blood out of the leg before inflating a pneumatic tourniquet on the thigh to prevent arterial flow. The result of this procedure is a bloodless extremity. One tactical combat tourniquet is a Stretch, Wrap, and Tuck Tourniquet (SWAT-T), TEMS Solutions, LLC, Abingdon, VA, USA. This rubberized wrap is a black identical version of the Esmarch tourniquet invented by Dr Esmarch over 100 years ago to keep an extremity bloodless during an amputation.¹⁰⁻¹²

One of the tourniquets currently carried by tactical medics is a SWAT-T. This could be used to exsanguinate the leg if placed distally and wrapped in a proximal direction. The process is clumsy and time consuming. However, an Internet search revealed that an Israeli emergency physician has invented a tourniquet to more rapidly accomplish exsanguination. The US Food and Drug Administration (FDA) has registered the HemaClear[®] tourniquet as a Class I device for exsanguinating a leg in orthopedic surgery.^{13,14} It has been found to be safe and effective for the purpose of exsanguinating a leg for bloodless orthopedic surgery on upper or lower extremities. The HemaClear[®] tourniquet is a single use device that is disposable and sterilizable. In the inventor's published study,⁶ they describe a repackaged version of the device called an Auto Transfusion Tourniquet. For orthopedic purposes, the goal is to compress the blood out of the leg, for the reasons mentioned previously, and after the surgery to allow the blood back into the leg for reperfusion. The inventor of this device, Dr Noam Gavriely (a professor of medicine and formerly an emergency physician and member of the Israeli Defense Force) provided samples for our testing. The 73-year-old female case study described in the opening paragraphs was the first patient on whom this device was used. She was an end-stage case; there were no other therapies left that could save her. The treatment with the HemaClear[®] ATT was dramatically successful; to have used it earlier in her clinical course would have been advantageous.

This device has already been vetted by the FDA for the indication of exsanguinating the leg. It has been shown to be safe and effective in that setting.¹⁴ As an FDA registered device, it is also clearly legal for any physician to use it "off label" if they feel it is indicated. Contraindications to use that are known include: deep vein thrombosis of the extremity; cancer or known infection of the extremity; and congestive heart failure. The device could be used on a hemorrhaging extremity or even on an open fracture provided it can be rolled over the injury. It is titratable, in that if the BP is restored with

the rapid auto transfusion of blood from the leg, it could be rolled partially down to the distal thigh or just past the knee if there is concern about the systolic pressure rising over 100 mmHg and increasing bleeding. An extremely important caveat is that removal of the device is to be done gradually after surgical correction of bleeding, and restoration of the blood volume. To remove it rapidly would be the same as the immediate loss of one liter of whole blood. From the resuscitation point of view the goal is to compress the blood out of the leg to maintain the core circulation and perfuse the vital organs, heart, lungs, brain, and abdominal organs, and to stop unnecessary perfusion of the legs or arms. The advantage of this single use device over the SWAT-T plus a tourniquet is that the ATT can be applied in 10 seconds. That is, in 10 seconds 500 cc of the patient's own blood can be transfused from the leg, where it is not vital, to the core circulation, and also eliminate 20% of the cardiac output demand from each leg.

Emergency medical personnel might recall the military anti-shock trousers (MAST) found in military ambulances 15 years ago. In fact, many providers were aware of cases where the MAST was lifesaving.¹⁵ In 1997, the National Association of EMS Physicians (NAEMSP) issued a position paper on the use of MAST. They found the evidence definitely beneficial in ruptured abdominal aortic aneurysm, and possibly beneficial in hypotension due to pelvic fracture, anaphylactic shock refractory to standard therapy, uncontrollable lower extremity hemorrhage and severe traumatic hypotension. However, many providers witnessed the rapid demise of a patient when the MAST was cut off or ripped off too rapidly. Understanding the physiology of blood supply provides an explanation. Sudden (less than 10 seconds) withdrawal of one liter of whole blood from a patient with a compromised blood volume causes an immediate cardiovascular collapse. The MAST did not stand up to critical evaluation, and studies showed it auto-transfusing only 5% of the estimated leg volume.^{16,17} In addition, the MAST had a safety pop-off valve making any pressure in the blood vessels over 110 mmHg systolic override the valve, with the result that the blood would be trapped in the leg by the MAST.

The HemaClear[®] ATT has the advantage of being titratable: the web roll can be cut off once the ATT has been applied, allowing visibility of injuries below. It is not affected by ascent or descent in a helicopter, a problem observed with the MAST.¹⁸ It is much less expensive, intended for single use, and is easy to carry. This device needs only minimal training to apply, though it does take some training

in the timing of removal. It does exactly what is needed in the pre-hospital combat arena. It allows additional time for extraction, transport, and definitive surgical treatment: it is the next evolution in tourniquets.

However, more evaluation of the tourniqueting concept is indicated. The authors of the present study are currently conducting an ED study on the use of this device in shock of all kinds, as theoretically the device should work in neurogenic, septic, anaphylactic, and hypovolemic shock. A study in postpartum hemorrhage is also underway, and field tests are being conducted presently in Afghanistan. A pre-hospital study application in a California Emergency Medical System is in process for a randomized prospective study.

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Disclosure

The authors of the study report no conflicts of interest in this work.

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