

Program of Instruction

Abdominal Aortic Tourniquet – AAT™

Overview

The AAT is focused at a significant capability gap identified by the Institute of Surgical Research for care on the battlefield: how to address uncompressible hemorrhage that is not treatable by a tourniquet in the leg, groin, inguinal region and pelvis. This significant capability gap focuses on treatment for a class of preventable deaths not previously treatable. The solution to this problem must be stable, easy to apply and completely stop the loss of blood. The AAT™ is capable of this, and animal and human studies have demonstrated its safety and efficacy.

The AAT™ provides a rapid application of pneumatic compression to the aorta at the abdominal-pelvic junction to occlude blood flow in the common iliac and inguinal arteries. The target of the compression is the aortic bifurcation, which has historically been identified in relation to the umbilicus or the superior margin of the iliac crests. Compression at this level is effective and safe and approved by the FDA. The device can be applied in about 45 seconds.

Difficult bleeds in the inguinal region continue to be a significant source of morbidity and mortality on the battlefield. Providing solutions for treating these wounds have direct life saving results. Wounds to the pelvis and inguinal region are now preventable causes of death.

The AAT™ is a circumferential device that utilizes a belt, windlass and pneumatic pressure to compress the aorta. The belt and windlass together greatly increase the stability of the compression. The pneumatic wedge shaped bladder provides focused pressure to squeeze the blood vessels passing through the lower abdomen and preventing flow. The research referenced below demonstrates the safety of up to one hour of application and its effectiveness in non-invasively cross-clamping the aorta or fully stopping all blood flow to the pelvis and lower extremities. In essence the AAT™ acts as a valve to figuratively 'turn the faucet off' and prevent the further flow of blood out of wounds below its application site.

Blood is the vital component to surviving blunt or penetrating trauma in the golden hour. It allows oxygen to be carried to the heart, brain and kidneys. Every drop of blood lost impacts survival. The AAT is the best solution for the prevention of shock in the casualty injured below the waist.

Primary Advantages of the AAT

- Speed of application (mean time of application 45 sec, faster than a single CAT application or any of the other junctional devices)
- Definitive cessation of arterial blood flow below the umbilicus
- Lower tissue pressures for increased comfort and decreased risk of secondary tissue and nerve injury
- The AAT is the most stable junctional device during patient movement due to not using a mechanical fulcrum that pulls away from the body during application
- The AAT is the only device to stop bleeding in interpelvic injuries which is a common complication in lower junctional trauma
- The AAT provides the capability to be used as a triage and assessment tool. First application allows a blood free field to identify wounds and apply appropriate interventions.
- No effect on respiratory effort or diaphragm movement during application
- It is the only device to show effectiveness when used in upper junctional bleeding
- It can be applied effectively to the axilla and base of neck and subclavian region
- It can also be applied to one inguinal region for one sided inguinal or leg injuries
- It is one device for all junctional bleeding

Program of Instruction – Instructor’s Notes

It is very important that the device be tightened before inflation. Through out the program of instruction special emphasis has been placed on this fact. In the instructions for use insert it is highlighted in more than one place. The tighter the device is prior to inflation, the more stable the device is during and after inflation.

Slide 1 – Title Slide

Slide 2 – AAT intro slide

“The AAT™ is a simple device incorporating basic functions of a buckle, windlass (similar to any extremity tourniquet), and hand bulb (similar to a blood pressure cuff). It utilizes minimal dexterity and fine motor control.”

Slide 3 – Solution for a Problem

“The AAT is focused at a significant capability gap identified by the Institute of Surgical Research for care on the battlefield: how to address uncompressible hemorrhage that is not treatable by a tourniquet in the leg, groin and inguinal

region. This significant capability gap focuses on treatment for a class of preventable deaths not previously treatable.. The solution to this problem must be stable, easy to apply and completely stop the loss of blood. The AAT™ is capable of this, and animal and human studies have demonstrated its safety and efficacy.”

“17 Lives lost in the last 10 years (Kragh 2011) as opposed to 2500 deaths in Vietnam from isolated extremity hemorrhage... this is DOW and misses KIA; just US. Only 1/17 was AIS 5. The point is that extremity hemorrhage has been successfully addressed”

“What remains is junctional hemorrhage and how to treat it. 1 out 4 deaths from bleeding are potentially preventable.”

Slide 4 – Mid Abdominal Pressure

The article “Control of Hemorrhage in Critical Femoral or Inguinal Penetrating Wounds—An Ultrasound Evaluation” written by Blaivas et al from the Medical College of Georgia demonstrated that centralized external pressure of 80-140 pounds (mean pressure 104.4 lbs) was enough to stop all flow in the common femoral arteries of patients studied. Blaivas utilize dumbbells with a pressure cone to apply the pressure.

This validated a practice taught to medics of placing a knee in the mid abdomen when trying to treat and survey patients with bad pelvic and leg injuries. It also serves as the basis behind the AAT’s creation and application.

Slide 5 – Aortic Compression

The AAT works differently than the Combat Ready Clamp (CRoC). The ability to stop all blood flow eliminates the possibility of the body shunting flow through collaterals to reach an injury in the lower extremities.

MAJ Walker UK Ministry of Defense showed that in 92 deaths only one would have been helped with the inguinal pressure the CRoC provides but all 92 would have been treated with the AAT

Slide 6 – Animal Study Video

In the video that is shown the common femoral artery and vein are transected. The AAT is positioned in the top of the screen on the abdomen of the pig. The bladder is inflated and arterial bleeding stops. Once initial compression is in place you will note some seeping of venous blood into the cavity. This is low volume and low flow seepage and could be addressed with minimal pressure.

Next, the bladder is deflated. Once deflated the arterial bleeding resumes and then the bladder is re-inflated. As soon as the bladder is re-inflated the bleeding stops. This is repeated once more.

The last portion of the video shows inflation with power Doppler flow ultrasound. The red pulsation of arterial flow in the common femoral artery stops as the bladder is inflated. Then the video time lapses 60 min to the end of the protocol when the AAT is deflated. As the bladder is deflated the red signature of arterial flow followed by the blue signature of venous flow is seen.

Slide 7 – Indications for Use

The inguinal region constitutes one of the most difficult problems of junctional bleeding faced in penetrating trauma. Junctional bleeding occurs in areas of the body that are not easily amenable to tourniquet application. They are generally the areas where the torso meets the extremities.

The AAT is applied at the navel before the Aorta splits off to go toward the legs. All flow is stopped in the common iliac arteries and further downstream in the femoral arteries as well.

Slide 8 – Contraindications for Use

The risks versus benefits of the device should be considered prior to any application. The dangers of junctional bleeding include imminent exsanguination and death. If direct pressure, extremity tourniquet application and hemostatics do not result in cessation of bleeding the Abdominal Aortic Tourniquet provides for a direct pressure capability to cease the flow of arterial blood below the application site.

Slide 9 – Device Components

Device components are described to the students.

Slide 10 – Instructions for Use (Emphasis on tightening prior to inflation)

The tighter the belt is prior to inflation (achieved by good firm pulling of strap to take out all slack and tight windlass application), the more stable and effective the device. A tight belt allows aortic compression at lower bladder volumes. Lower bladder volumes result in the device rising off the abdomen less than a fully inflated bladder. The higher the device rises off the body the less stable it is.

Slide 11 – Instructions for Use (steps listed)

Instructor provides overview of the application steps

Slides 12-15 show the steps using pictograms

Slides 16-19 show the steps using images from a training evolution

Slide 20 – Application: Helmet Cam Footage

This video shows a medic placing the AAT around a casualty's waist and applying the device successfully. From the moment the medic arrives on scene until the device is applied and the patient is ready to be placed on a litter is less than one minute.

Slide 21 – Inflating the Bladder (gauge depicted in detail)

100% of the human subjects had full occlusion at just under 250 mm Hg.

The inflation system incorporates a bleed-off design to limit pressures under 300 mm Hg. The bench testing on bladder failure shows that pressures over 1034 mm Hg can result in RF weld leaking or rupture. Inflation until the pressure indicator reveals a green strip indicates that the pressure in the bladder has reached 250 mm Hg. At 230 mm Hg, 100% of the human subjects had full occlusion of the flow in the femoral arteries.

If the device is inflated to pressures over 300 mm Hg the internal bleed-off mechanism in the gauge will allow enough air to escape to prevent sustained pressures greater than 300.

Slide 22 – Stabilization is the Key

This slide presents the instructor with another opportunity to drill home the idea that the tighter the device is secured the more stable the device will be during and after inflation.

Slide 23 – Transport Issues

Transport issues: The device uses pneumatic pressure in a closed system. When this system is taken to elevation relative to the altitude it was applied, there will be a change in ambient air pressure. As elevation increases ambient air pressure decreases. As this occurs internal pressure in the closed system will increase. The AAT is designed with a bleed off valve that prevents pressures in the system to exceed 300 mm Hg pressure. So on ascent the system will self adjust to keep the pressure in the green.

On descent the medical provider will need to watch the gauge and add air into the system if the gauge falls out of the green range. This effect will be exaggerated with larger changes in altitude.

Slide 24 – New Application Sites (overview)

There are three new sites of application for the AAT. The Groin, the axilla and the neck. These sites will be shown in detail in the slides to follow.

Slide 25 – Single Groin Application

This application site is for the single leg amputation of upper leg injury that a tourniquet cannot be easily applied. If there is any wounding above the inguinal ligament the traditional application site should be used. The single groin application site does not protect against all potential pelvic vascular injuries. It is quick to apply. The strap should be centered over the hips. Because it uses a great deal more surface area to displace tissue, it utilizes far less pressure than the other mechanical devices available; it is more comfortable and more stable during transport. As with other application sites, ALL slack must be removed from the device prior to inflation.

Slide 26 – Example of Single Groin Application

Soldier posing with the AAT in place with the strap around the hips instead of the waist.

Slide 27 – Axilla Application

The AAT is also an effective hemorrhage control device for subclavian artery and/or axilla injuries or single arm amputations. It is possible to displace tissues from the axilla that will stop the flow of blood through the subclavian artery. With lower pressures than what is required for the pelvis and aorta all bleeding can be stopped to the arm. This is effective even on a high arm or shoulder amputation. It has a very quick application time and can be anchored either around the contralateral shoulder or the neck. The use of a SAM splint is helpful as the pressure on the strap will be significant. It is stable in transport and provides a solution where none currently exists. As with other application sites, ALL slack must be removed from the device prior to inflation.

Slide 28 – Example of Axilla Application

Anchoring around the shoulder is demonstrated. Note the picture from the first civilian use and the fact that all the bleeding stopped because the device is causing pressure to be exerted on the proximal subclavian artery. The patient had a 6 cm disruption in his brachial to axillary artery. The AAT remains stable during transport.

Slide 29 – Base of Neck and/or Open Carotid Application

Injuries to the base of the neck and/or the vasculature of the carotid and proximal subclavian arteries are very difficult to control. When the AAT is applied in this area it acts as a large pressure dressing with the wedge directing the pneumatic pressure displacing the tissue towards the heart instead of laterally on the neck. The edge of the device is aligned with the jaw and when inflated there will be a tilting of the head, which could be an issue if there is concern for cervical spine injury. Data to date does not indicate a high chance of occurrence of cervical spine injury in penetrating trauma. Pneumatic pressure can work without skeletal deformity. The AAT can be placed securely and quicker, safer and more comfortable than mechanical compression. As with other application sites, ALL slack must be removed from the device prior to inflation.

Slide 30 – Example of Base of Neck and/or Subclavian Application

Anchoring the strap under the opposite axilla is more comfortable with a SAM splint or some other form of padding.

Slide 31 – PMCS Slide #1

Indications for inspection and replacement are presented. It is necessary to mention that the device is not a sterile device, so if the vacuum seal is broken but the package is not overtly damaged then the device is still ready to use.

Slide 32 – PMCS Slide #2

Actual PMCS list is reviewed. This is the list printed on the package insert.

Slide 33 – Device Removal

The AAT is safe and should not be removed until the patient arrives at a definitive surgical care capability. It is a proximal control device. Until another method of providing proximal control is ready the device should not be removed even if the application time extends beyond an hour.

Slide 34 – Device Issues

QA Point of Contact Information is provided to the students

Slide 35 – Questions?