Program of Instruction
Abdominal Aortic and Junctional Tourniquet – AAJT™

Overview

The AAJT 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 as well as the axilla and upper extremities. 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 AAJT™ is capable of this, and animal and human studies have demonstrated its safety and efficacy.

The AAJT™ 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 as well as the subclavian artery at the axilla placement site. The target of the compression for pelvic-junctional hemorrhage 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 target of compression for upper junctional bleeding is the axilla with the compression stopping blood flow in the proximal subclavian artery. The device can be applied in about 45 seconds.

Difficult bleeds in the junctional regions of the body, where the extremities meet the torso 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, inguinal and axilla region are now preventable causes of death.

The AAJT™ 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 and effectiveness in non-invasively cross-clamping the aorta or fully stopping all blood flow to the pelvis and lower extremities. In essence the AAJT™ acts as a valve to figuratively ‘turn the faucet off’ and prevent the further flow of blood out of wounds below its application site.

When applied to the groin, the AAJT™ is effective using less pressure than that required for the Combat Ready Clamp (CRoC) or Junctional Emergency Treatment Tool (JETT) to work. The large bladder of the AAJT™ applies pressure over a large surface area allowing for lower overall tissue pressure. This allows for a reduced risk of tissue and nerve injury than the CRoC and JETT.

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 AAJT™ is the best solution for the prevention of shock in the casualty injured below the waist, or in the upper junctional regions of the body.

Primary Advantages of the AAJT™

- The AAJT™ is the only device to have an approved indication for bleeding in the pelvis which is a common complication in lower junctional trauma
- It is the only device to save human life in upper and lower junctional bleeding
- It is the only device with human research that supports its safety and efficacy
- It is the only device with independent international validation of its effectiveness
- Speed of application (mean time of application 45 sec, faster than a single CAT application)
- Its is the only device simple enough to be applied by non-medical providers, since its application doesn't require knowledge of the vascular anatomy.
- It provides definitive cessation of arterial blood flow below the umbilicus, at the groin or in the axilla by stopping proximal subclavian artery flow.
- Lower tissue pressures for increased comfort and decreased risk of secondary tissue and nerve injury
- The AAJT™ 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 AAJT™ 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 diaphragm movement during application
- It can be applied to one inguinal region for one sided inguinal or leg injuries with pressures far lower than the CRoC or JETT
- It has a larger volume and more physiologically focused bladder design than any other pneumatic device.
- It is the only Class II Medical Device for junctional hemorrhage.
- 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 – AAJT™ intro slide

> "The AAJT™ 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 AAJT™ 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 AAJT™ 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. Balaivas utilize dumbells 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 AAJT's creation and application.

Slide 5 – Aortic Compression

> The AAJT™ 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 AAJT

Slide 6 – Indications for Use and Vascular Graphic

The graphic demonstrates the two placement sites for pelvic and lower junctional bleeding.

Slide 7 – Inguinal Compression

The AAJT™ works with less tissue pressures than the Combat Ready Clamp (CRoC) or the JETT. Lower tissue pressures reduce the risk of nerve and muscle damage as the ISR found with the CRoC in 2013.

Slide 8 – Inguinal/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 9 – Example of Single Groin Application

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

Slide 10 – Axilla Application

The AAJT™ 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 11 – 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 AAJT™ remains stable during transport.

Slide 12 – Axillary Compression

The AAJT™ works on upper extremity junctional bleeding by compressing soft tissue along the chest wall, stopping all the blood flow in the mid proximal subclavian artery.

Slide 13 – 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. The same is true for Inguinal and Axillary hemorrhage but there are no known contraindications for these areas.

Slide 14 – Animal Study Video

In the video that is shown the common femoral artery and vein are transected. The AAJT™ 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 vide time lapses 60 min to the end of the protocol when the AAJT™ is deflated. As the bladder is deflated the red signature of arterial flow followed by the blue signature of venous flow is seen.

Slide 15 – Device Components

Device components are described to the students.

Slide 16 – 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 17 – Instructions for Use (steps listed)

Instructor provides overview of the application steps

Slides 18-21 show the abdominal placement steps using pictograms

Slides 22-25 show the steps using images from a training evolution

Slide 26 – Abdominal Application: Helmet Cam Footage

This video shows a medic placing the AAJT™ 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 placed on a litter is less than one minute.

Slides 27-31 show the groin placement steps using pictograms

Slides 32-36 show the groin placement steps using pictograms

Slide 37 – 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 show 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 38 – 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 39 – 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 AAJT™ 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 40 – 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 41 – PMCS Slide #2

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

Slide 42 – Device Removal

The AAJT™ 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 43 – Device Issues

QA Point of Contact Information is provided to the students

Slide 44 – Questions?