HemaClear® Bloodless Surgical Field - the Anesthesiologist Perspective

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Synopisis

HemaClear® (HC) is a new device used to prepare a bloodless surgical field in limb surgery. It replaces the Esmach bandage, the pneumatic tourniquet with its accessories and the stockinet. It is an elastic, sterile single-patient use product that has sizes that cover from pediatrics to obese for both lower and upper extremities. Its superiority over the old pneumatic tourniquet method, from the procedure and surgeon's standpoint is accompanied by important advantages from the overall patient's safety and wellbeing as seen from the anesthesiologist's perspective. These include tissue mechanics, circulatory, hematology and logistical aspects which are reviewed below. In particular, the narrow footprint of the HC ring minimizes the amount of tissue under compression, reduces the stress and strain on the nerves and facilitates proximal placement for extended view bleeding-free procedures in mid-shaft femur and humerus/elbow cases. The sterile HC can also be placed close to the surgical incision thereby minimizing the amount of tissue under ischemic conditions. The near-perfect exsanguination prevents blood from being left behind to clot and accumulate cardio-depressive ischemic by-products (CO2, lactic acid, K+) as is manifested by post-tourniquet release shower of emboli and drop in blood pressure seen with the tranditional method. The use of the HC has been shown to reduce the need for post-op blood transfusion in bilateral TKA. Its use can reduce tourniquet time and OR time and the logistics of procurement and pre-op setting up is markedly streamlined.

The usual contraindications of the bloodless field preparation apply to the HemaClear® including the presence of DVT, infection and malignancy in the operated limb. Skin lesions are relative contraindications and peripheral vascular diseases should be viewed with caution and certainly with attempt to cut ischemia time to a minimum. The anesthesiologist should be aware of the fact that the device is designed and factory-calibrated to withstand an upper limit of systolic blood pressure (130, 160, 190 mmHg, depending on model). If the patient's BP rises above the rated level (e.g. due to pain), blood will penetrate the limb causing bleeding and disrupting the surgical procedure. The tourniquet time (in patients with normal circulation) is limited to 120 minutes. A second device can be applied in long procedures after a period of re-perfusion. Correct size and site selection is a shared responsibility with the surgeon. The overall rate of side effects is very small with no reported cases of long-standing tourniquet paralysis. Two cases of possible fat necrosis were reported in obese elderly patients with no consequences.

The HemaClear® is a cardiovascular product that is serving in orthopedic surgeon. As such, full understanding of its mechanics, physiology and clinical implications by the anesthesia team is essential. The material below is a brief review of these aspects.

Introduction

Establishing a bloodless surgical field for limb procedures is routinely achieved by exsanguination and arterial blocking. HemaClear® (HC), an elastic exsanguination tourniquet (EET), is now used instead of the traditional Esmarch bandage - pneumatic tourniquet combination. The aim of this note is to review the use of the HC device from the anesthesiologist's point of view, with emphasis on its advantages, pitfalls, contra-indications and side-effects. It is also intended to review the mechanics of the device-tissue interactions with respect to its much narrower footprint.

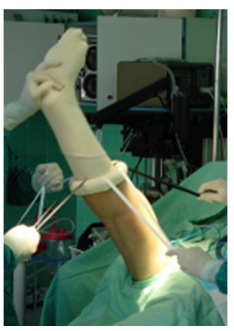

Image: HemaClear® XL model being rolled unto a leg.

Mechanics of Narrow Footprint EET

The HC occludes the arterial inflow into the limb with a tight elastic ring that remains in-place for the duration of the procedure (up to 120 minutes). Its width is about 1/7th of the

regular pneumatic tourniquet. When circumferential pressure is applied to the surface of the thigh or an arm, the pressure propagates inward to the center of the limb. To block arterial flow, it is necessary (and sufficient) to exert just enough pressure outside the artery to overcome the peak systolic blood pressure of the patient. When using the traditional wide pneumatic cuff, the same pressure generated in the cuff is uniformly distributed throughout the diameter of the limb and over nearly the entire width of the cuff (Figure 1a). As such, a cylinder of tissue with a volume that is equal the cross section area of the limb (e.g. for a thigh, A = Pi * r^2 = 3.14 * 100 = 314 cm^2) multiplied by the cuff's width (e.g. for 12 cm wide tourniquet, about 3.5 liters of tissue) is under significant compression for the duration of the procedure.

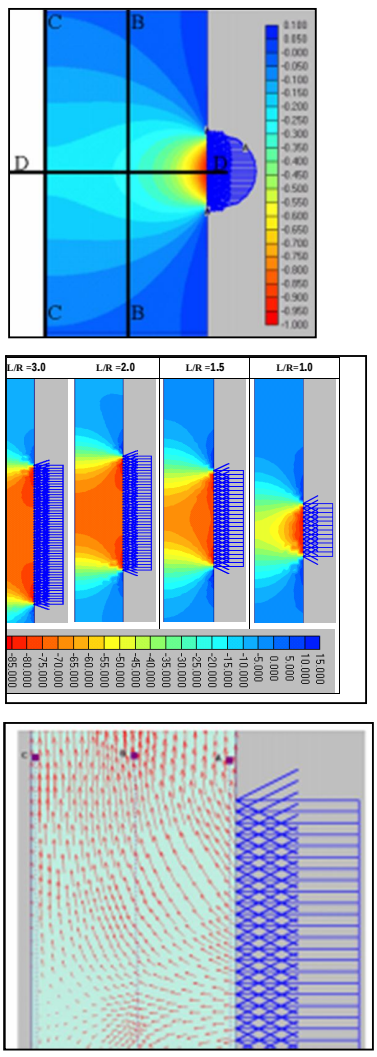

Figure 1: The images show the tissue pressure (stress) and motion (strain) when circumferential constricting force is applied to a limb. The pressure fields in 1a (top) and 1b (middle) are demonstrating by color coding the axial (along the limb) and radial (across the limb) gradients on a half cross section. Note that with the wide tourniquets (Length/Radius ratio: L/R=3.0 and 2.0) the pressure is uniformly high across the entire limb, but as the L/R gets smaller (right most panel in 1a and in 1b the tissue pressure dissipates quickly and is smaller than right beneath the device. Figure 1c (bottom) shows with arrows the axial migration of tissue elements as cause by a wide tourniquet (see below).

Figure 1 summarizes Blond's findings. They found that the best level of exsanguination was obtained with the Esmarch bandage. It was able to remove nearly 70% of the blood. The Pomidor, a device that is similar to, but smaller than the Rhys-Davies, was found to have removed slightly over 60% of the blood. Limb elevation was the least effective with no more than 45% of the blood was removed irrespective of the duration of holding the limb up.[1] As such, these studies clearly indicate that a substantial (eg. 30-55%) amount of the blood remains in the limb at the time the tourniquet is applied and blood flow ceases. No similar studies have been done so far with the elastic exsanguinating tourniquet, but multiple clinical studies have indicated that the exsanguination is near perfect (Fig. 2).[2]

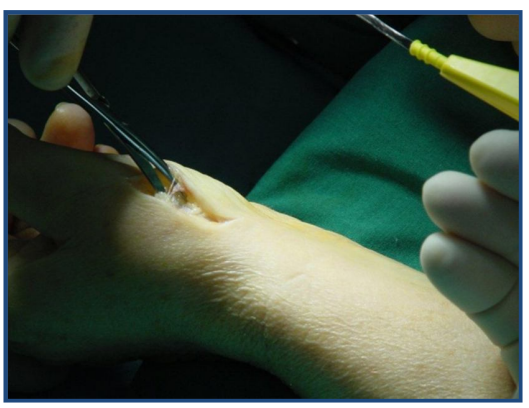

Figure 2. A nearly bloodless surgical field when using silicone exsanguinating ring.

Intravascular Coagulation

When blood stops flowing or becomes stagnant, it tends to coagulate and form fresh thrombi. Clot formation during tourniquet application has been demonstrated in 1979 in subhuman primates.[3] There are several factors that promote coagulation during total knee arthroplasty. These include reduced temperature, hypoxia and seepage of activated complement components from the incision site.

The time it takes for blood to coagulate from the onset of tourniquet application is under 6

minutes and is certainly less than 30 minutes[4]. With more than a pint of blood in the vessels of a normal sized leg. Incomplete exsanguination as outlined above will leave behind 120-250 mL of blood in the leg. When this residual blood clots, there is a certain degree of separation between the plasma and the clot so that the actual clot volume is probably 50-120 mL, depending on the pre-operative hematocrit.

The Events at Tourniquet Release

When tourniquet pressure is reduced ("tourniquet down"), blood floods into the limb first into the arterial side and shortly thereafter blood starts flowing in the veins. The blood flow sweeps with it the fresh thrombi from the veins into the inferior vena cava and into the right atrium. Multiple studies where the right atrium was monitored with trans-esophageal Doppler have identified a shower of echogenic material in the atrium in all the patients. Several of these studies are worth mentioning more in detail. In 2002, Hirota et al.[5] did a quantitative analysis of the extent of the material traveling across the atrium. They found a peak density of about 20% of the atrium cross sectional area. This peak occurred approximately 30 seconds after the release of the tourniquet and gradually subsided over the next 10-15 minutes.

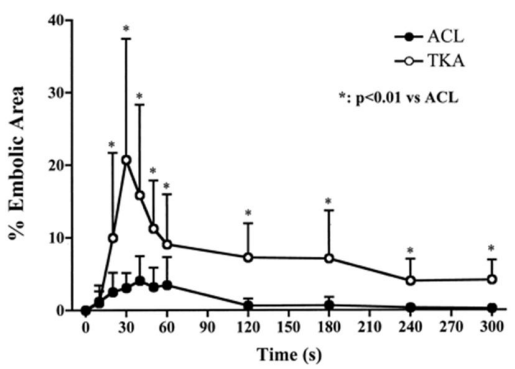

Figure 3. Time course of emboli formation in the right atrium (RA) after tourniquet release in the anterior cruciate ligament (ACL) and total knee arthroplasty (TKA) groups. *P < 0.01 versus ACL. All data are mean ± sd.

Another important publication is a study by Berman et al. in the JBJS in 1998.[6] In addition to documenting the fact that all the patients had echogenic material passing through their right atrium, they specifically evaluated the nature of the material. They inserted catheters into the femoral veins in the right atria in some of the patients that participated in the study, and aspirated blood immediately after the release of the pneumatic tourniquet. All the aspirates that contained solid material consisted of soft thrombus and did not contain fat, marrow, or cement material. The ongoing existing controversy on the nature of this echogenic material before the publication of this study was ended by these results.

Another study that shed light on this phenomenon was done by Parmet at al.[7] in 1998, where they compared the extent of the echogenic material in patients undergoing total knee arthroplasty with and without a pneumatic tourniquet. They found a 5.3 fold increase in the amount of material at the time of the tourniquet release in the tourniquet group compared to those patients where a tourniquet was not used. As such, it is clear from this study that the presence of thrombi is directly and unequivocally related to the stagnation of the blood in the leg.

Some of the studies attempted to correlate the duration of the application of the tourniquet with the extent of the thrombi recognized by the trans-esophageal Doppler. These studies did not show any statistically significant correlation. However, it should be noted that in all the studies tourniquet time was substantially greater than typical clotting time of blood. As such, one would not expect to see a correlation if in all patients clotting had already occurred. To date, no studies have yet been published on the extent of the echogenic material at the release of newer elastic exsanguination tourniquet.

Hemodynamic Effect of Thrombi Migration into the Right Heart

The clots that sweep through the right atrium continue into the right ventricle and the

pulmonary arteries, and eventually lodge in the more distal arteries and arterioles in the pulmonary circulation. There they occlude the blood flow, thereby diverting the blood into other parts of the lung. Pulmonary vascular resistance goes up and the afterload of the right ventricle increases. In most normal patients the right ventricle reacts by increasing its end systolic pressure, as well as the end diastolic pressure. However, the pulmonary blood flow may be impeded to a degree, leading to a transient reduction in the venous return into the left atrium and ventricle. It is safe to assume that the Frank-Starling mechanism will reduce the left ventricular contractility and cardiac output. The negative inotropic effect is compounded by the effect of the acidic blood coming from the legs' veins, which may also include high levels of carbon dioxide and potassium. During the period of occlusion of blood flow there is tissue hypoxia and a buildup vasodilator. These dilate the arterioles causing a decrease in vascular resistance. When tourniquet is released and perfusion is restored, blood flow is elevated leads to reactive hyperemia. The reactive hyperemia results in a washout of the acidic blood

The accumulated effect of these factors cause a sudden drop in systolic and diastolic blood pressure which is very familiar to anesthesiologists who care for patients undergoing TKA. The common practice is to infuse 560-1000 mL of fluids just prior to tourniquet release in anticipation of this pressure drop. As such, one may conclude that the effect of the pulmonary emboli at the time of the tourniquet release is not associated with the detrimental cardio pulmonary consequences of any lasting importance. However patients with preexisting conditions, such as pulmonary hypertension, COPD, congestive heart failure and related illnesses, should be given special attention to these effects.

Right-Left Shunt and Thrombi into the Arterial Circulation

In about 20%[8] of the population, the foramen ovale is closed by a detachable flap that prevents blood from moving from the higher pressure left atrium into the right atrium. This flap can open like a one way valve when the pressure in the right atrium rises above that on the left. This happens when emboli occlude the pulmonary circulation, as described in the previous section. This circumstance causes the right to left flow of blood which is saturated with thrombi from the limb clot. Once in the left side, the thrombi readily move into the left ventricle and are pumped into the arterial system. With the carotid arteries being the first branches out from the aortic arch in a straight line orientation, it is not surprising that at least some of these clots move into the cerebral circulation. This has been documented by trans-cranial Doppler in a number of studies that showed nearly 60% prevalence of echogenic material in the Circle of Willis with a peak at 50 seconds after the pneumatic tourniquet is released.[9] Other paths of the right-left shunt of blood and clots are through AV connections in the lungs that open up when pulmonary blood pressure rises.

Brain Infarcts Post Total Knee Arthroplasty

The first publication on cerebral emboli post TKA[10] failed to document cerebral infarcts by brain CT. However, a subsequent study by Monk et al[11] in 2005 clearly showed by MRI before and after TKA that 5 from 22 patients had new brain infarcts. The difference between the two papers is probably explained by the fact that small brain infarcts surrounded by edematous brain tissue are more readily detected by MRI than CT scan.

Post TKA Cognitive Dysfunction

The entity of reduced cognition after elective TKA is well known and well documented. The prevalence has been researched in a number of studies with observations that more than 40% of the patients have cognitive dysfunction seven days after surgery and

more than 15% still had cognitive dysfunction 3 months after surgery. The percentages are much higher than observed in other procedures by general surgeons with similar types of anesthetics. As such, the notion that this cognitive dysfunction has to do with the performance of the anesthesiologist is not supported by the evidence. On the contrary, it is quite plausible and at least indirectly documented that these cognitive changes are the result of cerebral emboli infarction.

Summary

A flow diagram below summarizes the events leading from incomplete limb exsanguination to cognitive dysfunction during TKA.

Conclusions

Prevention of blood stagnation in the exsanguinated limb seems to be the critical element in this chain of events described above. This can be done by avoiding the use of the tourniquet all together or by using a technology that exsanguinates the blood better than with the current methods (Esmarch, limb elevation, Rhys-Davis). HemaClear® is one such device that exsanguinates the entire blood from the limb (except the blood within the bone marrow).

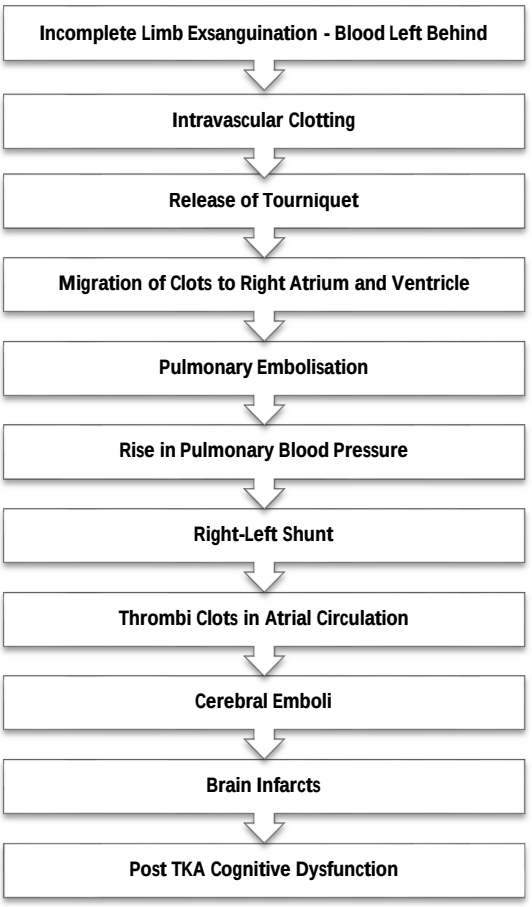

Figure 4. Cascade of events that link post TKA CD with incomplete leg exsanguination. See text for details.

[1] *Ibid.*

[2] Boiko M, Roffman M. Evaluation of a novel tourniquet device for bloodless surgery of the hand. .J Hand Surg [Br]. 2004;29B:185–187.

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[9] Sulek CA, et al. Cerebral microembolism diagnosed by transcranial Doppler during total knee arthroplasty. Anesthesiology. 1999; 91:672–6.
[10] *Ibid.*
[11] Monk TG, et al. The influence of tourniquet time on cerebral embolic events in elderly patients undergoing total knee arhtroplasty. Tallahassee (FL): National High Magnetic Field Laboratory; 2004. Report No.: 2004-NHMFL-Report165.