



INTENSE HYPERBARIC OXYGEN TREATMENT FOR ISOLATED LIMB

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ABSTRACT

Conventional hyperbaric oxygen treatment requires the whole patient be enclosed in a chamber and subjected to the increased oxygen pressure, even though the target for therapy might be a small ulcer on the foot. This approach means that out of considerations for the potentially harmful effects of hyperbaric oxygen on the lungs, brain and heart, the dives are limited in depth and time. Thus multiple treatment cycles are necessary.

This paper outlines a theoretical new approach wherein the limb is temporarily isolated from the body's circulation and hyperbaric blood is delivered to the limb by way of retrograde femoral cannulas with occluding balloons. Since the major organs of the body are not exposed to the circulating hyperbaric blood, dives can be deeper, as much as 5 Atmospheres Absolute, (1 ATA = 760 mm Hg; hence 5 ATA = 3800 mm Hg); and longer, possibly 6 to 8 hours.

Since, also, there is no contact with the liver or kidneys, much higher doses of vancomycin may be used concomitantly with the hyperbaric blood, possibly in the range of 10 to 20 grams. In the treatment of malignancies in the limb, similar increases in chemotherapy agents could be used.

Keywords: New Method Of Delivering Hyperbaric Treatment. Isolation Of Limb. Retrograde Femoral Cannulation.

INTRODUCTION:

Patients in the Intensive Care Unit with gas gangrene or necrotizing fasciitis of the foot and lower leg are often deemed "too sick" to tolerate trips to the Hyperbaric Unit for routine therapy. Instead they usually make only one trip, to surgery for an amputation.

Similarly, patients with worsening pyoderma gangrenosum lesions, or refractory osteomyelitis, also suffer an amputation if they cannot tolerate conventional hyperbaric treatments.

Among the major reasons for patients being unable to undergo hyperbaric treatments are: pneumothorax, pulmonary blebs, a history of thoracic surgery, emphysema, asthma, chronic sinusitis and upper respiratory infections, low ejection fraction of the heart, seizure disorders, claustrophobia, a history of ear surgery, sinus pain, uncontrolled high fever, congenital spherocytosis, obesity, diarrhoea and vomiting from antibiotic therapy, current treatment with bleomycin, doxorubicin, or disulfiram, and pregnancy. Outpatients are also subject to transportation and weather problems.

PROPOSED ALTERNATIVE TREATMENT:

Instead of placing the whole patient in a hyperbaric chamber, we considered the possibility of placing just the leg in a smaller cylinder constructed in a similar fashion to current hyperbaric chambers. (FIGURE 1). During treatment the patient could rest in bed as though they had a long leg cast.

This concept is partly based on the patent application by David Kaye of Osprey Medical Inc. (U.S. 9555183 B2)

submitted on 31st January 2017, in which he describes limb retroperfusion treatment using catheters with occluding balloons placed in the femoral artery and vein.

The big difference from Kaye's equipment, is the need to cope with blood containing oxygen dissolved at high pressures. This in turn would require bigger occluding balloons for the femoral vessels to prevent migration of the balloon. In addition, the sealing of the top of the chamber to the skin of the thigh would pose the need for special techniques, rather like the mirror image of sealing a wound vac, as we would be trying to *contain* 5 ATA of positive pressure (4,000 mm Hg), instead of 200 mm of negative pressure.

Because the lungs and the brain would not be exposed to the hyperbaric blood, treatments could be continuous, there would be no need for air breaks; and increased depths of 5 ATA would not be out of the question. Additionally, because the kidneys and liver would not be exposed to the perfusing blood, much higher doses of chemotherapy agents and vancomycin (10 to 20 G) could be administered. The addition of L-arginine would increase the efficiency of oxygen delivery to the diseased area (Boykin and Baylis, 2007).

This concept of regional hyperbaric therapy could cut costs and save a lot of time; as one 24 hour continuous treatment would be the equivalent of 16 dives lasting 90 minutes each. This would be a valuable approach to kill all the bacteria, but we would still need time for new tissue growth and actual wound healing. So possibly further treatments to address this latter concern could be at 3 or 4 day intervals.

An extracorporeal membrane oxygenator would be required to dissolve the oxygen in the perfusing blood, with the special need for a pressurized enclosure so that 5 ATA of oxygen could be used. High pressure tubing would take the blood to the femoral cannula.

It would be necessary to monitor the temperature and pH of the blood perfusing the limb. At intervals, it would be necessary to discard the blood containing toxic products from dead bacteria and necrotic tissue. This need not be whole blood as most of the oxygen is in solution, hence a hematocrit of 10 would be reasonable.

PRACTICAL PROTOCOL ENVISAGED

1. Patient brought to the Operating Room for insertion of heparin bonded plastic femoral cannulas, possibly percutaneously with ultrasound guidance, or using a cut down technique. Meticulous sterile technique is used (Coulson et al, 2016. and Pavlushkov et al 2017). The arterial and venous balloons are arranged to be side by side. They should be about 10 cm long.
2. Inflate arterial balloon first, then venous balloon. Commence circulation of blood in oxygenator circuit with addition of 5,000 units of heparin.
3. Paint skin corresponding to area over balloons and proximally with body adhesive like JOBST "It Stays" body fixative.
4. Slide on pre sized thigh washer, with correct sized hole to accommodate patient's thigh. Thigh diameters vary from 16 to 26 inches in adults.((FIGURE 2.)
5. Screw on leg chamber to washer, arranging padding to be under leg.
6. Inflate occluding circular balloon skin tourniquet on washer. Complete air tightness using "Flex Tape" combined with impregnating elastomer material. If necessary, a further orthopedic tourniquet could be applied to handle higher ATAs..(FIGURE 3).
7. Attach Tcom monitor to patient's foot. Close door at bottom of cylinder.
8. Increase ATA of circulating blood and simultaneously increase ATA in leg chamber so they correspond.
9. Maintain arterial blood pressure 100 mm Hg higher than chamber pressure.
10. At end of treatment, wash all residual vancomycin out of limb, then lower ATA back to 1. At this point let down occluding balloons so that leg circulation is reunited with body's.
11. Maintain a low dose of heparin in patient to prevent clots in femoral vessels.

DISCUSSION AND CONCLUSION

This approach of going directly to the disease site without involving major organ systems of body is reminiscent of the Minimally Invasive Direct Coronary Artery Bypass surgery approach (Coulson et al, 1997), which similarly seeks to avoid damage to the brain and kidneys by

avoiding the use of the heart-lung machine.

One of the unknown factors to be determined in the future, is the optimal use of this new hyperbaric treatment both in depth and timing once all the bacteria have been killed. Then the approach changes, and the focus is on stem cell migration and tissue repair and the migration of skin cells.

At the very least this new approach gives us the opportunity to avoid amputation in very sick patients. Additionally, it provides the possibility of a cheaper and quicker method of delivering hyperbaric medical therapy.

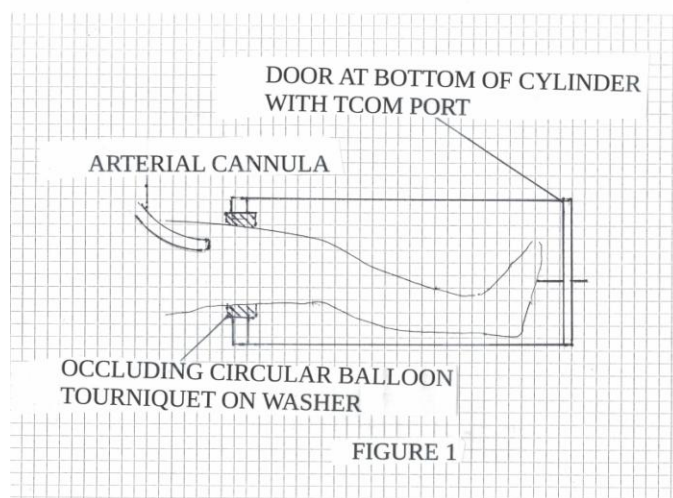


Figure 1. Patient's right leg in small hyperbaric chamber.

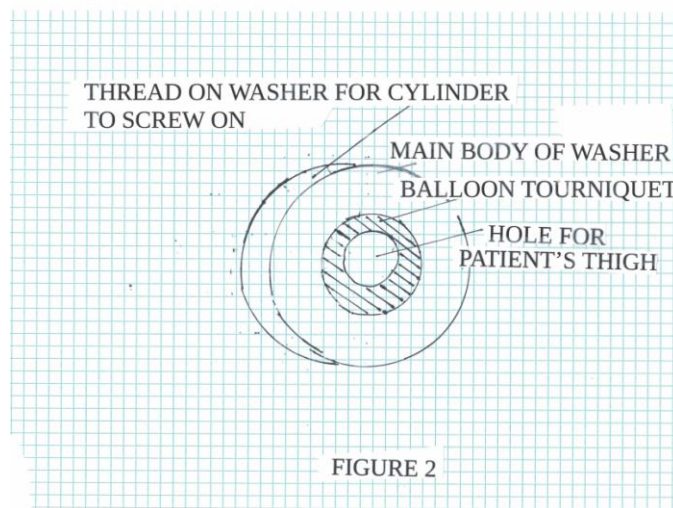


Figure 2. Washer with central hole for thigh.

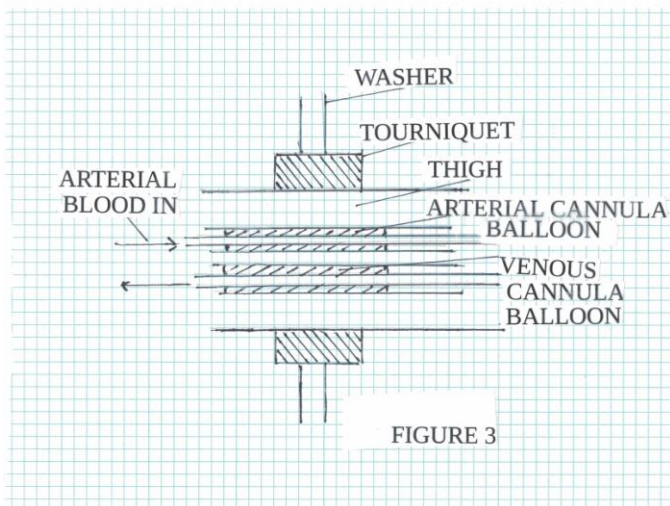


Figure 3. Inflated circular tourniquet in washer overlies occluding balloons in femoral vessels.

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