

Intermittent Pneumatic Compression for Av Fistula Maturation: A Promising New Concept

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Editorial

The continuing global increase in kidney disease presents a substantial healthcare burden, and is associated with cardiovascular diseases, diabetes, hypertension, as well as human immunodeficiency virus and malaria[#1].

Hemodialysis in end-stage renal disease requires continued vascular access, the preferred type being arteriovenous fistulae (AVF), which confers both a longer-term patency than arteriovenous grafts and catheters and fewer complications once established [#2]. However, AVF are affected by high incidences of non-maturation or primary failure, leading to care delays, increased catheter reliance and consequent complications, and increased morbidity, mortality, and healthcare expenditure [#3].

AVF maturation failures can involve a medley of factors, including physicians' case volume, care protocol-related factors, in-flow artery and vein characteristics, and patient comorbidities [#4]. The very nature of end-stage renal disease care can also mean that the radio cephalic veins are in poor shape by the time the decision to create an AVF is reached. "Often, when we come to creating the fistula, the veins are already collapsing and are not good enough to take the additional flow," described Dr Singh. "This is because of multiple hospitalizations, and needling and access to that same line for an IV or to give injections. This spoils the vein; either it thromboses or scleroses.

"The National Kidney Foundation Kidney Disease Outcome Quality Initiative (K/DOQI) guidelines talk about 'fistula first' and that we need to be preserving the veins as much as possible. But we have a time lag – a practical delay that happens between the diagnosis of chronic kidney disease (CKD) and the patient making up their mind to have a fistula. At that point, when you do a fistula, it doesn't mature fast. We could probably wait for the vein to be in a better state before we construct the fistula, but most of the time we cannot wait that long."

The K/DOQI guidelines advise that patients perform hand grip exercises to increase forearm vein distention, thereby encouraging fistula maturation [#5]. However, explained Dr. Singh, many patients are unable to carry these out. "The hand grip exercise is an active task," he said. "The patient has to be fit and healthy enough, and in a conscious state. Most of the renal failure patients we know are lethargic and are already quite

down by the time they get into the dialysis state, so we have an issue with getting them to do the exercises properly. That is the main concern.

"We still routinely ask them to do the exercises, though. But we always see that patients are not really complying with what we say, because it requires active involvement on the patient's part."

The Fist Assist is a compact wearable device that provides intermittent vein compression via a pneumatic balloon. This device, said Dr. Singh, may exceed the benefits of hand grip training and other approaches to accelerating vein dilation. "The intermittent compression is automatic," he explained. "Also, because it is blocking flow for periods of 20 seconds, the fistula that is created is actually bumping flow against resistance. This has a better chance of vein dilatation than just doing the hand grip exercises.

"We have also used these in combination, asking patients to wear the compression device as well as doing the hand exercises. We have seen that this actually gives additional benefit."

Two studies of the Fist Assist device have been conducted so far [#3,6]. The first demonstrated the safety of the device, included 30 patients with stage 5 CKD who received AVF and Fist Assist (its cuff transmitting a pressure of 60 mmHg for 20 s, then deflating to 10 mmHg for 55 s, cyclically), and 15 control patients who received a sham device (which inflated to 10 mmHg, then deflated to 0 mmHg)[#3]

The second study looked at device safety and the effect of intermittent compression on vein size of radio cephalic and brachiocephalic fistulas (RCF; BCF). The Fist Assist was worn 15 cm proximal to fistulas for 6 hours per day for 30 days. The 43 patients in the treatment arm included 24 with BCF and 19 with RCF, and a further 16 control patients received a sham device. Vein diameter was measured at outset and at 30 days by duplex measurement. Statistical analysis indicated a significant increase in mean vein dilation in the RCF treatment group relative to controls at one month, at 5, 10 and 15 cm proximally from the anastomosis site. Similar findings were obtained when data pertaining to BCF and RCF patients were combined. Interestingly, at one month, over 60% vein diameter increase

was only achieved in the RCF, suggesting that the Fist Assist device may perform better in maturation of RCF than in BCF.[#6]

Patients in this study tended to opt for BCF over RCF, Dr Singh noted, commenting: “We always prefer the distal-most vein. This is the standard in creating a fistula, because if the RCF fails, we still have a more proximal vein at the cubital fossa where we can make another fistula. Irrespective of whatever we do, and however good the fistula is, they will have a lifespan of anywhere from two to five years. They are eventually going to block.

“Generally, there should be a very strong reason why we wouldn’t do a RCF. Even if a patient opts otherwise, we do try to convince them of the benefits. But sometimes there are patients who are a little apprehensive of RCF, especially those who do a lot of writing or hand-written work.

“We also notice that, when we gain consent for a fistula and inform patients that the vein size is small at the wrist and bigger at the elbow, and that we will first attempt a RCF and move higher up if this doesn’t work – some patients don’t want to take that chance. They don’t like the risk, and they will tell us to go straight up to the cubital. Most of the time, this is what happens. They would rather make sure that it is working.”

Going on to discuss longer term follow-up, Dr Singh continued: “When we were designing the second trial, we looked at what the size of the vein was, how much dilatation there was, were the fistulas good to use, and how quickly the temporary access catheters came out. But once the fistula was put to use, we didn’t really follow that up. Once the needling starts, there is a practical problem of assessing vein size and diameter. It would be ideal to follow these patients up at six months. We haven’t done that, although we hope to do this somewhere down the line.” Dr Singh added that the Fist Assist Clinical Trial (FACT), conducted by the University of Chicago Medical Center Institutional Review Board (IRB), has begun enrollment and seeks to follow patients for three months to assess the longer term effects of the device [#7].

European approval of the Fist Assist device is expected soon, noted Dr Singh in his concluding remarks. He also stressed the importance of improving fistula maturation: “There is a need, for patients with kidney problems or those who are getting into dialysis, for their veins to be much better prepared.

“We don’t know the long term behavior of the Fist Assist, but whatever we have done so far has shown good results. There is a global need, especially regarding patients with diabetes – a rising trend – and those with renal failure. It would really make an impact for these patients. Once an access has failed, a lot of these patients don’t really have much chance. They then have to go in for a graft or other modes of dialysis, each of which have their limitations. A native artery-vein fistula is always better.”

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