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**Does Far Infrared Therapy Reduce the Incidence of Arteriovenous  
Fistula Malfunction in Patients with Renal Disease Undergoing  
Hemodialysis?**

Parker Barrett, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## **Abstract**

**OBJECTIVE:** The objective of this selective evidence based medicine review is to determine whether or not far infrared therapy reduces the incidence of arteriovenous fistula (AVF) malfunction in patients with renal disease undergoing hemodialysis.

**STUDY DESIGN:** Review of three primary randomized controlled trial studies published from 2007-2013.

**DATA SOURCES:** Three peer-reviewed randomized controlled trials studying the effectiveness of far infrared therapy in the preservation of native arteriovenous fistula function in patients with chronic kidney disease requiring hemodialysis. Data searches done in PubMed, CINAHL Plus and EBSCOhost.

**OUTCOMES MEASURED:** Primary outcome measured was episodes of AVF malfunction due to stenotic complication. After randomization, patient outcomes were monitored and recorded over the span of 12 months to assess the effectiveness of far infrared therapy at preventing AVF malfunction. AVF malfunction was defined as any stenosis-related change in the AVF resulting in blood flow rate <200 ml/min (which requires surgical intervention or angioplasty). Infection, aneurysm formation and steal syndrome were not considered stenosis-related.

**RESULTS:** All three articles demonstrated a lower incidence of AVF malfunction in patients treated with far infrared therapy. The studies in question demonstrated zero incidence of any adverse effect.

**CONCLUSIONS:** This review reinforces the author's conclusions that FIR therapy, a non-invasive technique, is a useful modality for the prevention of complications requiring surgical intervention and the preservation of arteriovenous fistulas. These conclusions should not be extrapolated to patients with artificial AV grafts.

**KEY WORDS:** far infrared therapy; arteriovenous fistula; hemodialysis

## **Introduction**

Malfunction of vascular access is the most common cause of increased morbidity and need for hospital admission in patients receiving hemodialysis.<sup>5</sup> A technique capable of extending the life of a vascular access port without complication would have potential to improve the lives of the millions of people who require dialysis, as well as save the US an estimated billion dollars in health care costs annually.<sup>4</sup> This paper evaluates three recent RCTs which address the efficacy of far-infrared therapy at reducing the incidence of stenosis related arteriovenous fistula (AVF) malfunction.

AVF's are commonly the first choice for vascular access patients with stage 3 or 4 kidney disease because they are the access method with the lowest rates of infection and clotting problems.<sup>5</sup> The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH) estimates 398,861 ESRD patients were being treated with some form of dialysis in 2009. Being a Physician Assistant in the ED, primary care, internal medicine, surgery, nephrology and probably others will require knowledge of kidney dialysis and the treatment mechanisms currently available to this patient population.

The estimated annual cost of vascular access related morbidity to the US is \$1 billion dollars.<sup>4</sup> The exact number of healthcare visits each year is not known, but according to the NIH, at the end of 2009, more than 871,000 people were being treated for ESRD, 398,861 of which were receiving dialysis.

AVF malfunction remains the biggest obstacle to maintaining successful hemodialysis. The most common source of complication is stenosis and/or thrombosis at the site of the AVF, which alters flow state.<sup>5</sup> Hemodialysis access fistulas alter fluid flow patterns within the vessel.

Hemodialysis also requires frequent cannulation of the AVF. Over time, intimal hyperplasia occurs secondary the frequent irritation by cannulation and in areas of turbulent blood flow, which is generally at the created anastomosis. Hyperplasia results in decreased patency and further alteration of flow pattern. Decreased flow through the area can then result in thrombosis and eventual occlusion. A specific flow rate ( $>200$  ml/min) is required for adequate hemodialysis. These intravascular conditions synergistically create an environment prone to complication. It is important to prevent complications interfering with hemodialysis for the obvious reason that without adequate hemodialysis access, patients with end stage renal disease cannot receive the treatment allowing for their survival and must shift to alternate forms of dialysis with greater inherent risk of infection.

There is no currently accepted or widely used therapy which prevents the formation of intimal wall lesions and subsequent complications at the AVF site.<sup>6</sup> Problems arising from thrombosis and stenosis of the AVF are dealt with as they arise, which typically involves either stent placement or angioplasty depending on the preference of the physician.<sup>6</sup>

Far infrared (FIR) therapy is a non-invasive technique that is being proposed as a means to prevent complications at the AVF site and thus sustain AVF patency. It entails the administration of electromagnetic wavelengths via an external transmitter. Treatment involves placing a radiator device above the surface of the AVF for a period of minutes several times per week. Far infrared therapy can be done while undergoing hemodialysis treatments. Intervention specifics are listed in Table 1.

Authors suggest administration of FIR therapy improves endothelial function and prevents pathogenic changes associated with increased risk of AVF malfunction. Specifically,

the therapy has vasodilatory effects, prevents intimal hyperplasia, decreases oxidative stress and suppresses inflammation.<sup>2</sup> Thus, a therapy such as this could reduce morbidity and cost associated with AVF complications.

### **Objective**

The objective of this selective EBM review is to determine whether or not far infrared therapy is an efficacious way to reduce the incidence of stenosis-related AVF malfunction in patients receiving hemodialysis.

### **Methods**

Articles designated for this selective evidence based medicine review have proven to be adequate to investigate the objective. The articles consist of three randomized control trials. The articles were selected using the key words: far infrared therapy; arteriovenous fistula (AVF); hemodialysis. The author of this selective EBM review, Parker Barrett, conducted the research in Cochrane, PubMed, CINAHL Plus and EBSCOhost in January 2014. All articles were published in Chinese and English languages in peer-reviewed journals. Articles were chosen if they assessed patient oriented outcomes and included patients with CKD requiring hemodialysis, patients with native AVF, and population age greater than 18. Articles were excluded if they were review articles, non-patient oriented outcomes, and population age less than 18. Statistics were reported using p-values, relative risk reduction (RRR), absolute risk reduction (ARR), numbers needed to treat (NNT). P-values less than 5% were considered statistically significant.

In Lin et al. (2013)<sup>3</sup>, a prospective randomized controlled trial, inclusion criteria were patients 18-80 years old with CKD and  $eGFR = 5-20 \text{ mL/min/1.73m}^2$ , recently created upper extremity venous-to-arterial anastomosis and patients not anticipated to receive dialysis or renal

transplant within three months. FIR therapy was initiated 2 days postoperative anastomosis creation 3 times weekly for 12 months. Before starting hemodialysis, 40 minutes of FIR was done 3 times weekly at home or clinic. After beginning dialysis, FIR therapy was done for 40 minutes 3 times weekly during hemodialysis at clinic. External far infrared therapy (via FIR emitter) set at a height of 25 cm above the surface of the AVF.

In Lin et al. (2007)<sup>1</sup> and Lin et al. (2013)<sup>2</sup>, both prospective randomized controlled trials, the inclusion criteria were identical and as follows: patients receiving 4 hours hemodialysis 3 times weekly for at least 6 months via upper extremity venous-to-arterial anastomosis, in patients without interventions within the past 3 months. FIR therapy was done for 40 minutes 3 times weekly during hemodialysis at clinic for 12 months. External far infrared therapy (via FIR emitter) set at a height of 25 cm above the surface of the AVF.

The demographics of the studies included are demonstrated in Table 1. All three studies used untreated control groups for comparison. Patients were censored (withdrawal in Table 1) for reasons other than AVF malfunction, i.e. those with renal transplant, death with a functioning access, shift to peritoneal dialysis for reason other than stenotic complication, loss to follow up or non-stenotic complications (infection, aneurysm, steal syndrome).

Randomization accounted for differences in patient comorbidities. All three studies compared clinical characteristics of FIR treated and control groups, including age, gender, the length of time since AVF creation, history of AVF malfunction, and prevalence of hypertension and diabetes. Statistical analysis showed no significant difference between the two groups in all cases (p-values > 5%).

### **Outcomes Measured**

Outcomes measured included number of episodes of AVF malfunction secondary to stenotic complication. After randomization, patient outcomes were monitored and recorded over the span of 12 months to assess the effectiveness of FIR therapy at reducing the incidence of stenotic AVF malfunction. AVF malfunction was defined as any stenosis-related change in the AVF resulting in blood flow rate  $<200$  ml/min (which requires surgical intervention or angioplasty). Infection, aneurysm formation and steal syndrome were not considered stenosis-related.

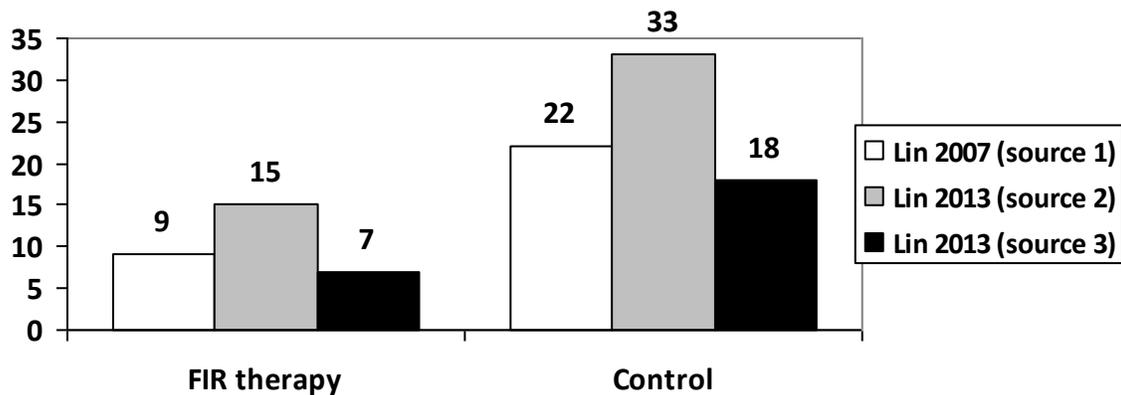
**Table 1: Demographics and Characteristics of included studies**

<b>Study</b>	<b>Type</b>	<b># Pts</b>	<b>Age (yrs)</b>	<b>Inclusion criteria</b>	<b>Exclusion Criteria</b>	<b>W/D</b>	<b>Intervention</b>
<b>Lin, 2007<sup>1</sup></b>	RCT	145	18-80	(i) receiving 4 h of maintenance HD therapy 3 times weekly for at least 6 months (ii) using a native AVF as the present vascular access for >6 months, without interventions within last 3 months (iii) creation of AVF by venous-to-arterial anastomosis in upper extremity	AV graft as the first vascular access.	18	Far-infrared radiation via emitter set at a height of 25 cm above the surface of the AVF for 40 min during hemodialysis 3 times per week.
<b>Lin, 2013<sup>2</sup></b>	RCT	280	18-80	(i) receiving 4 h of maintenance HD therapy 3 times weekly for at least 6 months (ii) using a native AVF as the present vascular access for >6 months, without interventions within last 3 months (iii) creation of AVF by venous-to-arterial anastomosis in upper extremity	AV graft as the first vascular access.	34	Far-infrared radiation via emitter set at a height of 25 cm above the surface of the AVF for 40 min during hemodialysis 3 times per week.
<b>Lin, 2013<sup>3</sup></b>	RCT	122	18-80	(i) CKD and eGFR = 5-20 mL/min/1.73m <sup>2</sup> (ii) Recently created upper extremity venous-to-arterial anastomosis (iii) Patients not anticipated to receive dialysis or renal transplant within three months	AV graft as the first vascular access.	14	Far-infrared radiation via emitter set at a height of 25 cm above the surface of the AVF for 40 min during 3 times per week (during hemodialysis once it has begun)

## Results

All three studies compared FIR therapy to untreated control groups and thus data breakdown was experimental vs. untreated. All relevant data was presented in dichotomous form, easily assessed for treatment effect on complication incidence. Figure 1 depicts the raw incidence of stenosis-related AVF malfunction over the span of 12 months in all three studies. All three studies showed zero incidence of adverse effect, such as skin burn or allergy to therapy.

**Figure 1: Incidence of AVF Malfunction within 12 Months**



Lin et al., 2007<sup>1</sup> demonstrated a statistically significant reduction in AVF malfunction incidence ( $P < 0.01$ ), with 12.5% (9/63) of FIR treated patients and 30.1% (22/64) of untreated patients developing new AVF malfunction. Absolute risk reduction was calculated as 17.6%, while the NNT was calculated as 6 (Table 2). Relative risk reduction was found to be 58.5%. This suggests a 17.6% reduction in stenotic complication incidence and that 6 patients must be treated with FIR therapy to prevent one AVF malfunction. The relative risk reduction indicates a 58.5% reduced risk of stenotic malfunction in FIR treated patients.

Lin et al. 2013<sup>2</sup> observed a statistically significant reduction in stenotic AVF malfunction incidence, with 12.6% (15/119) of FIR treated patients and 27.5% (33/120) of untreated patients developing new AVF malfunction ( $p = 0.004$ ). Absolute risk reduction was calculated as 14.9%, while the NNT was calculated as 7 (Table 2). Relative risk reduction was found to be 54.2%. This suggests a 14.9% reduction in stenotic complication incidence and that 7 patients must be treated with FIR therapy to prevent one AVF malfunction. The relative risk reduction indicates a 54.2% reduced risk of stenotic malfunction in FIR treated patients.

	p-value	RRR	ARR	NNT
<b>Lin et al., 2007<sup>1</sup></b>	<0.01	0.585	0.176	6
<b>Lin et al. 2013<sup>2</sup></b>	0.004	0.542	0.149	7
<b>Lin et al. 2013<sup>3</sup></b>	0.02	0.586	0.170	6

Lin et al. 2013<sup>3</sup> observed a statistically significant reduction in stenotic AVF malfunction incidence, with 12% (7/60) of FIR treated patients and 29 % (18/62) of untreated patients developing new AVF malfunction ( $p = 0.02$ ). Absolute risk reduction was calculated as 17.0%, while the NNT was calculated as 6 (Table 2). Relative risk reduction was found to be 58.6%. This suggests a 17.0% reduction in stenotic complication incidence and that 6 patients must be treated with FIR therapy to prevent one AVF malfunction. The relative risk reduction indicates a 58.6% reduced risk of stenotic malfunction in FIR treated patients.

## **Discussion**

Native arteriovenous fistulae are the most superior form of vascular access for hemodialysis, due to lower infection rates and greater durability.<sup>5</sup> AVF failure necessitates other access modalities with higher risk for infection and subsequent sepsis, making preservation of

the native fistula of the utmost importance.<sup>5</sup> Far infrared therapy is a non-invasive technique which could potentially be a useful modality for the prevention of thrombotic complications requiring percutaneous or surgical declotting and the preservation of native arteriovenous fistulas.

The precision of statistical values across the three studies (Table 2), consistent study parameters, and adequate sample sizes speak well in support of the authors conclusions.

Few of the current approaches to preventing AVF thrombosis are supported by statistical efficacy. Neither antiplatelet therapy nor systemic anticoagulation has proven to be effective in thrombosis prevention.<sup>6</sup> Avoidance of unnecessary venipuncture and fish oil (4 g per day) are the only current measures routinely recommended for prevention of AVF thrombosis.<sup>6</sup> Stenosis is generally addressed as it becomes apparent with percutaneous angioplasty. Considering the low number of currently available preventative techniques and the lack of apparent adverse effects, FIR therapy could prove to be a beneficial adjunct to hemodialysis.

Sample sizes were adequate for analysis of statistical significance. Compliance was 100% due to the fact that FIR treatment was tied to hemodialysis. Study limitations include the lack blinding in the control group. Blinding for future studies would require the use of a sham device similar in appearance to the FIR transducer. Despite lack of sham, results suggest efficacy beyond that of the placebo effect.

The most concerning limitation of the results listed above is the singular institution and authors responsible for the conduction of all three studies. Lin and colleagues of the Yang-Ming University of Taiwan have put forth excellent data, but reproduction by unaffiliated colleagues is

necessary. Also, all study participants were native to the region, so investigation as to whether ethnicity has any effect on treatment outcome is desirable.

Little investigation has been done into the cost of making far infrared therapy available at hemodialysis facilities, or any form of cost-benefit analysis for that matter. A formal investigation into the annual cost of stenotic AVF malfunction vs. the savings allowed for by making far infrared therapy available on a large scale is needed.

### **Conclusion**

The data assessed in this EBM review suggest far infrared therapy does significantly reduce the incidence of arteriovenous fistula malfunction in patients undergoing hemodialysis. Patients receiving FIR therapy required fewer interventions in all three studies. Further research is needed to determine if the reduction of complication incidence can be extended to patients with graft AVF ports. Reproduction of effects by another group of researchers would also be desirable.

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