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Cephalic vein dilatation at the elbow by preoperative supervised forearm exercise depends on adherence to therapy: Results from the randomized controlled single-blind PINCH trial

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A Part of Sage

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Abstract

Background: Maturation failure may be as high as 30%–60% of arteriovenous fistulas (AVF). Forearm exercise postoperatively has shown potential in increasing blood vessel size in patients with end-stage renal disease and may promote maturation of AVFs. Little evidence exists on the impact of pre-operative forearm exercises on the increase of vascular diameters. Aim of this study was to evaluate the effect of supervised forearm exercises on vascular diameters and AVF maturation.

Methods: The PINCH trial is a single-blinded, randomized controlled trial on supervised forearm exercises compared to no exercise 6 weeks before AVF creation. Forty-eight patients were included. Primary endpoint: vascular diameters after 6 weeks of exercise. Secondary endpoints: cephalic vein diameters and blood flow 6 weeks after surgery and change in vascular diameters between baseline and after exercise after tourniquet application (vascular compliance).

Results: A non-significant increase of cephalic vein diameters at the elbow after exercise was found. Subgroup analysis of patients that showed increased forearm force after 6 weeks of training, revealed an increased diameter of the cephalic vein at the elbow with tourniquet inflation (+0.73 vs –0.25 mm, $p=0.037$) and a greater increase in compliance of the cephalic vein at the elbow (+0.61 vs –0.34 mm, $p=0.045$), when compared to patients without exercises. No difference in cephalic vein diameters at the level of the wrist, or in AVF maturation was found (50% $p>0.999$).

Conclusion: The PINCH study was a randomized trial to evaluate the effect of pre-operative, supervised forearm exercises on vein diameters in patients with end stage kidney disease, and the first to evaluate supervised forearm exercises in this population. This trial shows that response to forearm exercise relies on adherence to the training program, with a positive effect on cephalic vein diameters at the elbow and a positive effect on the cephalic vein compliance without change in maturation rates.

Keywords

AVF, exercise, maturation, maturation failure, vein diameter

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Introduction

In the Netherlands almost 2000 people depend on renal replacement therapy per year, of which 1400 require a vascular access^{1,2} and arteriovenous fistulas (AVFs) are the preferred method.³ To function properly, a 6-week maturation period is needed to achieve adequate diameter for cannulation and sufficient blood flow for hemodialysis. AVF maturation is considered successful if, 6 weeks after surgery, the fistula supports a flow of at least 500 mL/min and has a diameter of at least 4 mm.⁴

The creation of an AVF as distally as possible decreases the chance of hemodialysis-access induced distal ischemia (HAIDI) and preserves the possibility of more proximal AVF creation. Moreover, this limits cardiac complications due to high flow AVF and subsequent high cardiac output.⁵ The first choice for vascular access thus is a radiocephalic fistula (RCF) at the wrist or a snuff box RCF.⁶ However, rates of RCF maturation failure may be as high as 30%–60%.^{7–10} Clearly, more methods to improve AVF maturation rates are needed.

Small diameter blood vessels and low blood flow are known causes for maturation failure of AVFs. Forearm exercise has proven to increase the diameter of the cephalic vein in hemodialysis patients with recently created AVFs.¹¹ When applied routinely by ESKD patients without AVFs, forearm exercise improves cephalic vein diameter within 6 weeks.¹² In stage 3–4 ESKD patients these beneficial changes can even be achieved within 4 weeks.¹³ Similar results regarding venous distention were achieved in the contralateral (non-AVF) arm of hemodialysis patient.¹⁴ Based on these small, non-randomized studies, international guidelines recommend regular forearm exercise in the first months *after* AVF creation.⁴ Our hypothesis is that *pre-operative* exercises may result in larger diameters at the time of surgery and will facilitate more distal AVF creation. The aim of this single blind, randomized controlled trial was to assess the impact of pre-operative forearm exercises on venous diameters and the possibility to create RCFs. The current manuscript adds detail and perspective to the report on primary outcome previously published as a research letter. In this publication we conclude that a moderate effect on vasodilation is to be expected from well-executed forearm exercises in patients with adequate strength at baseline. The ideal composition, which will be a trade-off between intensity and burden, of a training program should be studied and further established.¹⁵

Materials and methods

Full methods can be found in the Supplemental Data.

Study design

The study design was previously described and approved by the medical ethical board (NTR6382).¹⁶

Planned surgery type was based on the results of the preoperative duplex. Patients aged >18 years with a radial artery diameter >1.6 mm and a cephalic vein diameter >1.9 mm without tourniquet were considered eligible for RCF. All patients aged >18 years that were scheduled for AVF and had a cephalic vein diameter >1 mm at the wrist level were eligible for inclusion in this study.

At baseline, all patients in the intervention group received instructions and a training schedule containing supervised and monitored exercises for 10 min, three times daily for a total of 6 weeks. After 6 weeks, duplex examination was repeated. In the intervention group, the burden of the exercise was assessed and recorded in the file by the physiotherapist, along with weekly measurements of forearm strength and arm circumference. The arm circumference was always measured by the same physiotherapist, 5 cm distal to the elbow crease.

Endpoints

The primary endpoint was increase in cephalic vein and radial artery diameters after 6 weeks of forearm exercise. Secondary endpoints included cephalic vein diameters and blood flow 6 weeks after surgery, vascular compliance, and blood flow postoperatively. Additionally, maturation rate and early failure or intervention after 6 weeks in both groups was evaluated. Maturation was defined as a diameter ≥ 4 mm and flow >500 mL/min, in accordance with the ESVS guidelines, or clinically matured because it was punctured/used for hemodialysis. An additional aim of the study was to investigate whether this training method was feasible in this population.

Histological and immunohistochemical assessment

In addition we performed histological assessment of pre-operative derived venous samples to see if there was any difference in smooth muscle cells or collagen between pinch patients and the control group. We only collected tissue if there was venous material available peroperatively. Details are described in the extensive methods section in Supplemental Data.

Results

Patient inclusion

In total, 66 patients were eligible for inclusion and 48 patients consented and were randomized. Nine patients were withdrawn from the study after inclusion, but before starting the training schedule. A flow chart of the inclusions is presented in Figure 1. No patients were lost to follow-up after start of the training schedule.

Fourteen out of 17 (82%) patients performed $\geq 75\%$ of the time adequate exercises as recorded by the application on the tablet and physiotherapist reports.

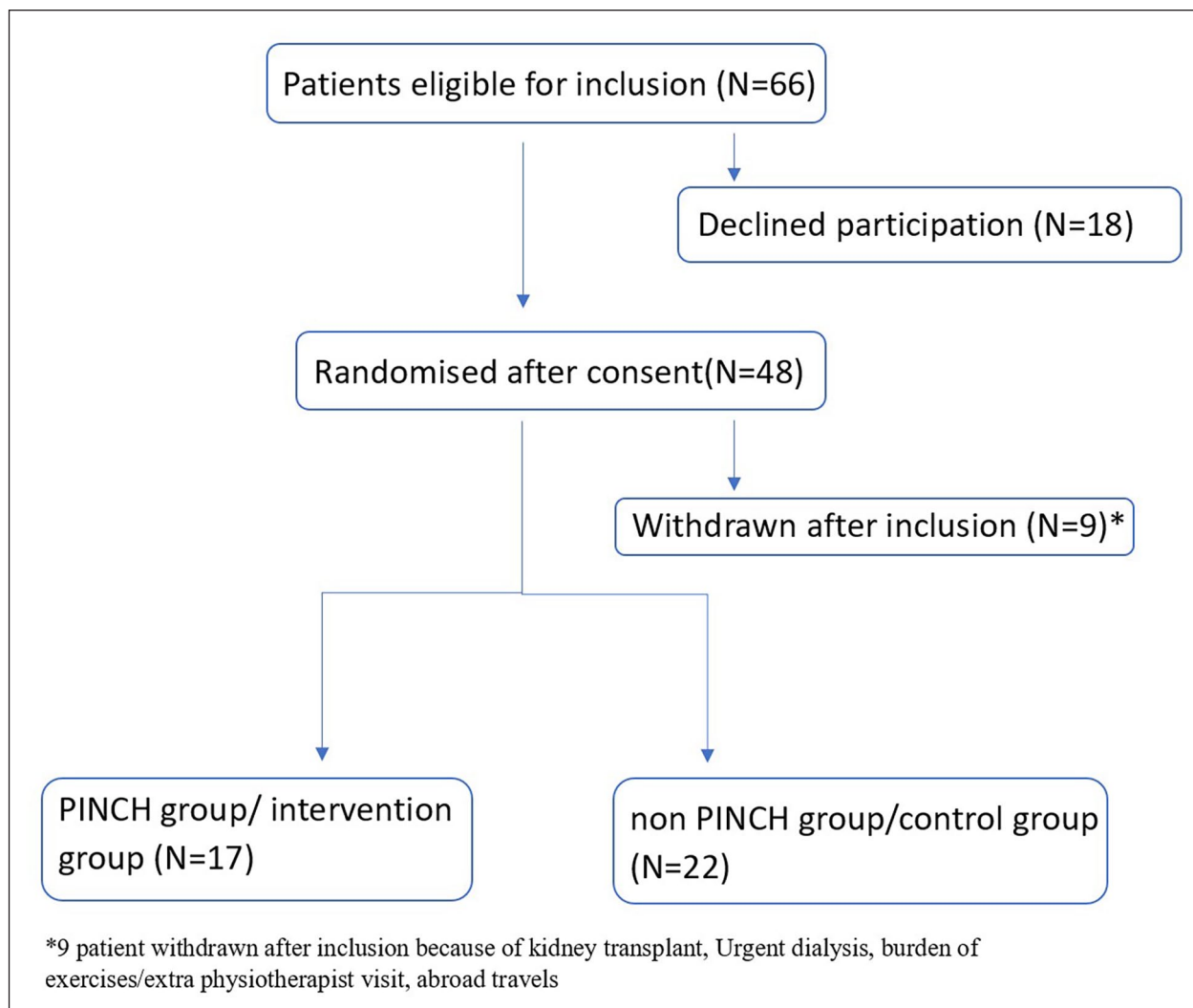


Figure 1. Flow chart of patient inclusion.

*Nine patient withdrawn after inclusion because of kidney transplant, Urgent dialysis, burden of exercises/extra physiotherapist visit, abroad travels.

Baseline characteristics

Patient characteristics are presented in Table 1. None of the baseline characteristics showed significant differences between the two groups.

Therapy adherence and forearm strength and circumference

Fourteen of 17 patients (82%) performed the exercises adequately at least 75% of the time. Only one patient reported that the app and the game provided extra motivation to practise. Two patients reported some fatigue at the end of a pinch session during the last minutes. Four patients initially needed to pause for a minute within the 10 min exercises. The pauses were fewer and shorter after 2–3 weeks of training. Four patients experienced the weekly visits to the physiotherapist on top of the other hospital appointments as burdensome.

Training effect, as measured by strength and arm circumference, increased in the PINCH group after 6 weeks. Average arm circumference, measured 5 cm distal to the elbow cease, increased by 0.44 cm ($p < 0.001$). Average pinching force increased by 2.75 kg ($p = 0.006$). An overview is presented in Figures 2 and 3.

Vascular diameters

Vascular diameter measurements at baseline duplex ultrasound are presented in Table 2. Overall, control patients (no pinch) had larger diameters. Significant larger diameters were found in the cephalic vein in the middle lower arm, the cephalic vein at the elbow and in the ulnar artery.

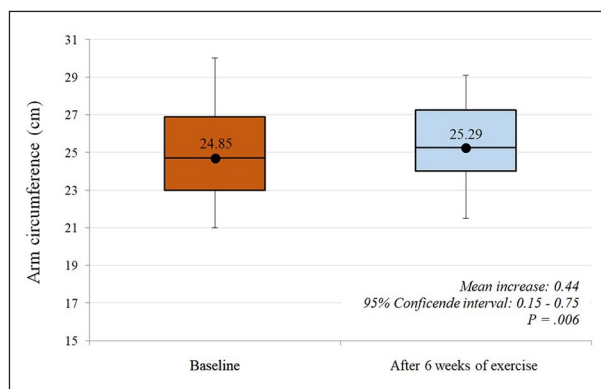
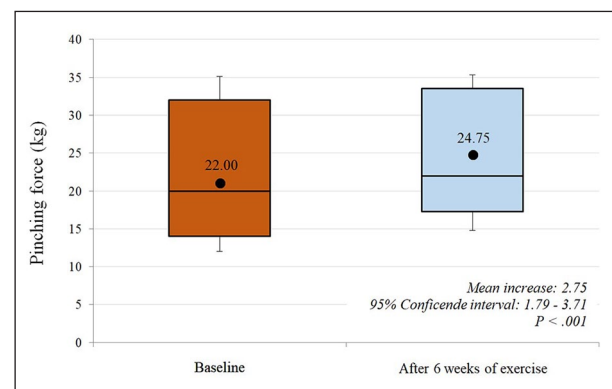
Vascular diameters after 6 weeks are presented in Table 3. Pinching patients showed an increase in cephalic vein diameters at the elbow level (increase $+0.56 \pm 1.19$ mm, $p = 0.050$). The subgroup of Pinching patients with increased pinching force showed significantly greater increases in the

Table 1. Patient characteristics at baseline.

Patient characteristics	Non pinch group (n = 22)	Pinch group (n = 17)	p-Value*
Pinching force (kg)		21.8 ± 0.9	
Arm circumference (cm)		24.9 ± 2.6	
Systolic blood pressure (mmHg)	143 ± 20	143 ± 19	0.95
Ipsilateral CVC before surgery (%)	1 (4.5)	1 (5.9)	>0.99
Demographics			
Age (years)	66.6 ± 8.9	65.6 ± 7.6	0.71
BMI (kg/m ²)	28.9 ± 8.8	27.7 ± 5.2	0.61
Gender (% male)	54	52	0.89
Smoking (%)	9	11	>0.99
Ethnicity (% Caucasian)	57	55	0.89
Cause of kidney failure			
Auto immune disorder (%)	2 (9.1)	1 (5.9)	>0.99
Obstructive/postrenal (%)	1 (4.5)	1 (5.9)	>0.99
Diabetic nephropathy (%)	12 (54.5)	11 (64.7)	0.52
Hypertension (%)	0 (0.0)	1 (5.9)	0.43
Autosomal dominant polycystic kidney disease (%)	6 (27.3)	3 (17.6)	0.70
Unknown (%)	1 (4.5)	0 (0.0)	>0.99

Systolic blood pressure: Mann-Whitney *U* test. Age and BMI: Independent *T*-test. Other: chi-square test or Fischer's exact test.

*p-Value for non-pinching patients versus pinching patients.

**Figure 2.** Boxplot of arm circumference in pinch group at baseline and after 6 weeks of forearm exercise.**Figure 3.** Boxplot of pinching force in pinch group at baseline and after 6 weeks of forearm exercise.

vascular diameters of the cephalic vein at the elbow with tourniquet (increase +0.73 ± 1.31 mm, *p*=0.037). Furthermore, there was an increase in compliance of the cephalic vein at the elbow (Increase +0.61 mm ± 1.34, *p*=0.045). No significant differences were found in the cephalic vein at the level of the wrist. Diameters of the radial artery did not significantly increase in the PINCH group after 6 weeks of exercise. Also in the PINCH group with a significant increase in PINCH force there was no increase in arterial diameters after 6 weeks of exercise, as shown in Table 3.

Surgery and postoperative follow up

Maturation rates 6 weeks postoperatively are presented in Table 4. In the control group 17 patients underwent RCF

and 4 patients BCF surgery and 1 patient received an arteriovenous graft (AVG) despite being initially planned for AVF surgery. In the pinch group, 12 RCAFV's, 3 BCAFV's, and 2 brachio-basilic fistulas (BBAVF) were performed. None of the patients that were originally scheduled for BBAVF could undergo RCF after pinch training.

Six weeks after surgery, maturation rates were not significantly different between groups. AVF maturation was achieved in 44% of the RCAFV's and 100% of the BCF's in the pinch group and 40% of the RCF's and 75% of the BCF's in the no pinch group. There was no significant difference in early failures or postoperative interventions between the PINCH and no PINCH group. An overview of events within 3 months after surgery is provided in the Supplemental Table 1.

Table 2. Vascular diameters and compliance at baseline.

Vascular parameters at baseline	Non pinch group (n = 22)	Pinch group (n = 17)	p-Value*
<i>Vascular diameter preoperatively (mm) (SE)^a</i>			
Without tourniquet			
Cephalic vein (wrist)	2.45 (0.23)	2.06 (0.16)	0.20
Cephalic vein (elbow)	3.73 (0.29)	3.04 (0.35)	0.13
Cephalic vein (middle lower arm)	2.74 (0.18)	2.02 (0.18)	0.010
Cephalic vein (middle upper arm)	3.58 (0.32)	2.86 (0.25)	0.093
Radial artery	2.54 (0.13)	2.53 (0.13)	0.95
Brachial artery	4.85 (0.16)	4.19 (0.32)	0.056
Ulnar artery	2.22 (0.14)	1.78 (0.08)	0.014
With tourniquet			
Cephalic vein (wrist)	2.67 (0.25)	2.41 (0.18)	0.42
Cephalic vein (elbow)	4.54 (0.32)	3.57 (0.33)	0.045
<i>Vascular compliance preoperatively (mm)^b (SE)^a</i>			
Cephalic vein (wrist)	0.22 (0.07)	0.35 (0.09)	0.25
Cephalic vein (elbow)	0.81 (0.17)	0.45 (0.23)	0.21

^aStandard Error of the Mean

^bDifference between vascular diameters before and after tourniquet inflation.

*p-Value for independent sample T-test (non-pinching patients vs pinching patients).

Histological and immunohistochemical assessment

The presented tissue samples (Figure 4(a)–(h)) demonstrate the veins used for AVF creation in both Pinching and Non Pinching patients. General morphology based on Movat's pentachrome staining (Figure 4(a) and (e)) did not show any obvious pathologies such as calcification in all patients. A consistent collagen deposition with an absence of fibrotic changes were observed (Figure 4(b) and (f)). Endothelial cell layers were intact and cells were closely aligned (Figure 4(c) and (g)). No evident signs of disturbed smooth muscle cell alignment (Figure 4(d) and (h)) could be observed. All vein samples showed an even distribution of the smooth muscle cells and comparable levels of extracellular matrix (Figure 4(d) and (h)).

Discussion and conclusions

To our knowledge, the PINCH study is the first blinded randomized controlled trial (RCT) investigating the impact of preoperative forearm exercise on target vein diameters and the first to compare directly and remotely supervised exercises. This trial shows that responsiveness to forearm exercise depends on adherence to the program, with a positive effect on cephalic vein diameters at the elbow and cephalic vein compliance (with and without tourniquet). However, there was no effect on maturation, vein diameters at the wrist level, or the creation of more distal AVFs.

Cephalic vein diameters and compliance are significant predictors of AVF maturation. In a study of 158 subjects, intraoperative vein diameter was a significant predictor of functional AVF maturation.¹⁷ Similarly, a large retrospective study of 1383 AVFs showed that cephalic vein

diameters <2.5 mm were linked to significantly higher risks of non-maturation.¹⁸ Moreover, the difference in vein diameter before and after dilation has been proposed as a predictor of AVF maturation.¹⁹ A separate study also found a correlation between venous distensibility and AVF maturation,²⁰ with venous distensibility closely resembling vascular compliance as measured in this study. The increase in cephalic vein diameter and compliance seen here is clinically significant and may contribute to better AVF outcomes in future studies focused on AVF maturation. Mid-forearm, elbow, or upper arm fistulas may benefit most from the observed vasodilative effects.

After the PINCH trial inclusions started, a systematic review on preoperative interventions for AVF maturation was published. This review concluded that hand exercise is the predominant intervention to promote maturation, but that methodological heterogeneity exists, and more well-designed RCTs are needed.²¹

One pilot study, involving 17 subjects, demonstrated significant increases in cephalic vein diameter after 4 weeks of isometric hand exercises.²² Remarkably, diameters in the contralateral, untrained arm also improved. The only other RCT on preoperative exercises before AVF creation, the “physicalfav” study, found similar, even more pronounced results.²³ After 6–8 weeks of unsupervised upper and forearm exercises, both venous and arterial diameters significantly increased, resulting in the creation of more distal AVFs, though no reduction in primary failure rates was observed. While these findings were more pronounced than those in the current study, there were key differences in demographics, methodology, and results.

The PINCH study population is similar to the “physicalfav” trial in terms of age and comorbidity, but venous and arterial diameters were smaller at all time points. For

Table 3. Increases in vascular diameters and compliance after 6 weeks.

Vascular changes 6 weeks postoperatively	Non pinch group (n = 22)	Pinch group			
		All patients in pinch group (n = 16)	p-Value*	Patients with increased pinch force (n = 13)	p-Value **
<i>Vascular diameter increase (mm) (SE)^a</i>					
Without tourniquet					
Cephalic vein (wrist)	-0.09 (0.16)	0.04 (0.22)	0.65	-0.06 (0.29)	0.93
Cephalic vein (elbow)	0.09 (0.26)	0.23 (0.39)	0.77	0.12 (0.52)	0.96
Cephalic vein (middle lower arm)	0.14 (0.18)	0.53 (0.16)	0.11	0.54 (0.20)	0.16
Cephalic vein (middle upper arm)	0.22 (0.26)	0.76 (0.21)	0.12	0.68 (0.24)	0.27
Radial artery	0.09 (0.12)	0.00 (0.12)	0.63	-0.01 (0.14)	0.063
With tourniquet					
Cephalic vein (wrist)	-0.08 (0.21)	-0.04 (0.22)	0.90	-0.19 (0.27)	.73
Cephalic vein (elbow)	-0.25 (0.26)	0.56 (0.30)	0.050	0.73 (0.38)	.037
<i>Vascular compliance increase (mm)^b (SE)^a</i>					
Cephalic vein (wrist)	0.03 (0.09)	-0.08 (0.13)	0.50	-0.13 (0.17)	.35
Cephalic vein (elbow)	-0.34 (0.26)	0.33 (0.32)	0.11	0.61 (0.39)	.045

^aStandard Error of the Mean.

^bIncrease in difference between vascular diameters, before and after tourniquet inflation.

*p-Value for independent sample T-test (non-pinching patients vs all pinching patients).

**p-Value for independent sample T-test (non-pinching patients vs pinching patients with pinch force increase >0.0 kg).

Boldface P-values indicate statistical significance

Table 4. Bloodflow, vascular diameter, and maturation rate 6 weeks postoperatively per access type.

Access type	Non pinch group ²¹				Pinch group ¹⁵				p-Value*	Overall maturation
	Acute failures	Diameter (mm)	Blood flow (mL/min)	Maturation rate**	Acute failures	Diameter (mm)	Blood flow (mL/min)	Maturation rate**		
Total	2/21 (10%)	4.73	767	9/19 (47%)	4/15 (27%)	4.72	553	6/11 (55%)	>0.99	15/30 (50%)
RCFs	2/17 (18%)	4.53	751	6/15 (40%)	3/12 (25%)	4.38	507	4/9 (44%)	0.58	10/24 (42%)
BFCs	0/4 (0%)	5.50	890	3/4 (75%)	1/3 (33%)	6.25	759	2/2 (100%)	>0.99	5/6 (83%)

*p-Value for Fishers' Exact Test for difference in maturation rates (non-pinching patients vs pinching patients)

**Maturation defined as flow >500 mL/min and diameter at least 4 mm at duplex ultrasound.

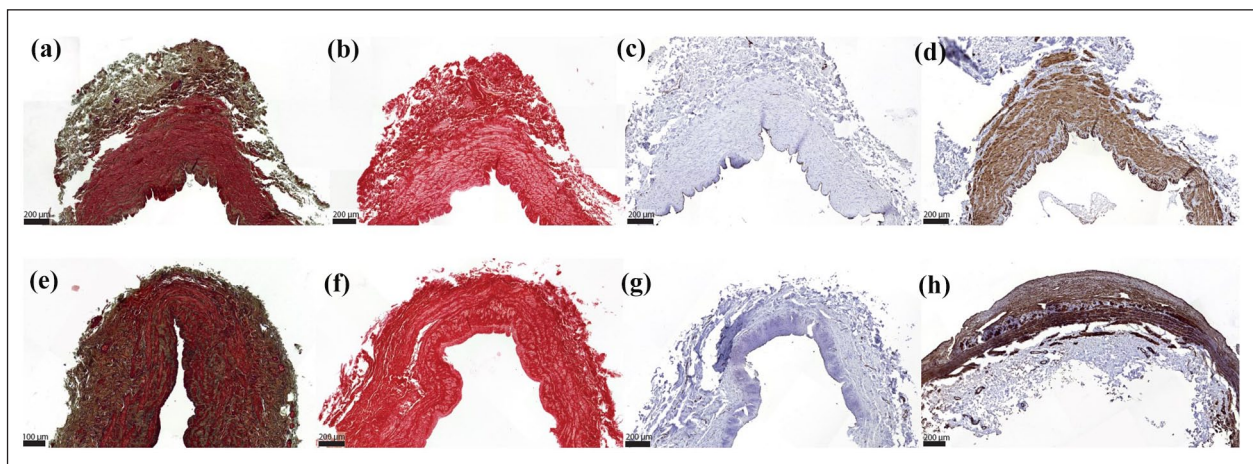


Figure 4. Representative tissue samples. Upper panel. Representative tissue samples of non pinching patient. (a) Movats Pentachrome staining. (b) Sirius Red staining. (c) CD31 staining. (d) Smooth muscle actin staining. Lower panel. Representative tissue samples of pinching patient. (e) Movats Pentachrome staining. (f) Sirius Red staining. (g) CD31 staining. (h) Smooth muscle actin staining.

instance, the baseline cephalic vein diameter at the wrist was 0.74 mm smaller in the PINCH study. According to Poiseuille's law, this could result in 2.6 times lower flow at surgery, and intraoperative flow is a known predictor of AVF maturation.²⁴

Handgrip strength, measured by dynamometry, was also 6 kg lower in the PINCH group (22 kg vs 28.4 kg in the "physicalfav" group), and the training effect was 60% of that observed in the physicalfav trial. Since handgrip strength correlates with clinical frailty in vascular patients,²⁵ these findings suggest worse venous competence and physical condition in the PINCH cohort. Preoperative forearm exercises may therefore be particularly beneficial for patients with better baseline strength. Smaller cephalic vein diameters (<2.0 mm) and diabetes are independent risk factors for failing wrist radio-cephalic AVFs²⁶ and the higher proportion of diabetic patients in this study may have further diminished the effect of training on vein distensibility.

There are four key methodological differences between the PINCH and physicalfav trial.²³ First, the current study involved 6 weeks of training, while the physicalfav study used an 8-week protocol. Previous research indicates that even 4 weeks of handgrip training in ESKD patients can improve venous dilation.^{27–29} Given this, the PINCH study opted for a three-times-daily, 10-min exercise routine over 6 weeks to balance training benefits with minimal burden on patients and avoid surgery delays. Second, the study's use of blinded ultrasound investigators and surgeons minimized bias. Third, to control for factors like temperature and hydrostatic pressure affecting vasodilation,³⁰ the PINCH study employed a standardized duplex protocol, enhancing reproducibility. Lastly, weekly physiotherapist supervision and real-time monitoring via a digital tablet optimized training adherence, a crucial factor for success in vascular surgery exercise programs.³¹

Although no study has yet demonstrated a significant beneficial effect of preoperative forearm exercise on AVF maturation, vascular dilation has been observed. A limitation of the current study is that it was not powered to investigate maturation outcomes. This was intentional, as it was first necessary to assess the effects of the exercise program on vascular dimensions before proceeding with a larger trial focused on maturation. The physicalfav trial, powered to detect differences in primary failure rates (i.e. non-maturation), found no significant effect of forearm exercise. However, the physicalfav trial resulted in more distal AVFs, which could have led to lower maturation rates, as forearm fistulas are known to have poorer maturation rates than upper-arm fistulas.^{18,26} This could have negatively impacted maturation rates in the physicalfav intervention group.²³

In conclusion no significant effect on maturation, vein diameter at the wrist level, or creation of more distal AVFs was observed in the PINCH trial. However, preoperative forearm exercises can moderately enhance vasodilation, especially in patients with better baseline strength. Future

studies should optimize the training protocol based on the findings of this and previous trials, balancing intensity with patient burden.

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Supplemental material

Supplemental material for this article is available online.

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