Treating Intermittent Claudication and Rest Pain.
A New Approach

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- No conflict of interest

Medical Treatment of Claudication and Rest Pain

- Suppression of tobacco

- Supervised exercise

- Cilostazol, Anti-platelets drugs, Statins

- Control of Risk Factors

Medical Treatment of Claudication and Rest Pain

We made two observations:

1) Female patient, 84 years old. She could walk only ten steps, suffered intestinal angina, she came severely dehydrated after an episode of diarrhea.

2) A 74 year old patient had several surgical and endovascular attempts to treat a severe ischemia of the left lower extremity. He was admitted because rest pain and pallor of the left foot. Oral mucosa was dry and he drunk only one glass of water the day before.

Medical Treatment of Claudication and Rest Pain

The common factor of both patients was dehydration.

Both patients had a significant improvement of symptoms after proper hydration in less than 48 hours.

We organized a prospective trial of patients with claudication and/or rest pain who did not respond to standard treatment after a minimum of 5 months.

We obtained the approval of the Ethical Committee of the Hospital, patients signed an informed consent.

36 patients accepted to sign in the pilot group, final number of patients was 132

Medical Treatment of Claudication and Rest Pain

Protocol:

Adult patients with disabling claudication or rest pain who failed

to improve after 5 months of complete medical treatment. Patients

with past history of CHF or renal insufficiency were excluded. 132 patients

signed the informed consent, median age was 72.5 years (67-77), 94 were

males. Mean intermittent claudication was 100 meters. 22 patients complained of

rest pain.

Medical treatment continued as before the trial was initiated, Only Cilostazol and diuretics were

Discontinued.

Complete physical examination was performed including blood and urinary tests .Color duplex performed.

Ankle/brachial index was recorded and cutaneous temperature determined

Medical Treatment of Claudication and Rest Pain

Protocol:

Time and distance to claudication was determined using a treadmill at 3.5 miles per hour.

Subjective pain sensation was recorded (0=no pain, 10=intense pain).

Medical treatment continued in the same way than before starting the protocol. Cilostazol and diuretics were discontinued.

Two and a half liters of fluid (water, milk, soup) and 0.6 g/Kg of albumin (Egg white and albumin powder) were administered every 24 hours

Physical examination and blood and urinary tests were performed weekly including electrolytes.

Medical Treatment of Claudication and Rest Pain

Protocol:

After 6 weeks and 6 months all tests were repeated and subjected to statistical analysis.

Protocol was continued to complete 12 months and new patients were incorporated.

Medical Treatment of Claudication and Rest Pain

Results:

131 patients drunk 2.5 liters of fluid or more. All patients were alive after 6 months.

All patients who complied with the protocol, had a significant increase of skin temperature in the feet. Initial temperature of the dorsal first toe: median 29,95 degrees Celcius, Confidential Interval (CI) (28 to 31)
Dorsal temperature first right toe (final) Median   30,65 degrees CI (29,300 to 31,468)
The difference was statistically significant
Wilcoxon test (paired samples) Two-tailed probability   p:0,0454

Medical Treatment of Claudication and Rest Pain

Results:

After treatment all patients who complied with the protocol (131)

Increased the time and distance to claudication from 100 meters to 535

meters at 6 weeks p<0,0001, and time to claudication increased from

1.3 to 6.3 minutes p<0.0001. At 6 months 34.17% of the patients

Improved further to 735 meters to claudication and 8.79 minutes to

time to claudication.

Medical Treatment of Claudication and Rest Pain

Results:

131 patients had significant decrease in pain sensation $p<0,0001$; when

ankle/brachial index was > 0, it increased in all patients, from 0.6 to

0.75 $p<0,0001$.

Albumin concentration in serum increased to more than 4 grams per

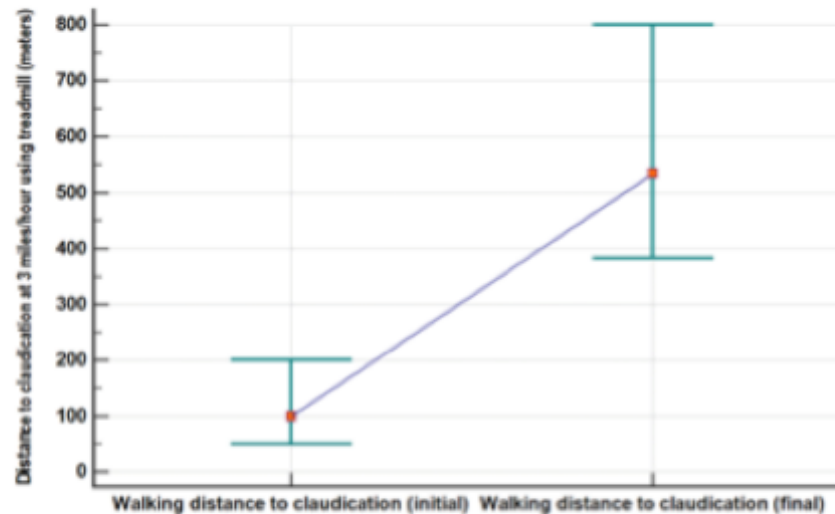deciliter in all patients.

Cutaneous Temperature at 6 weeks
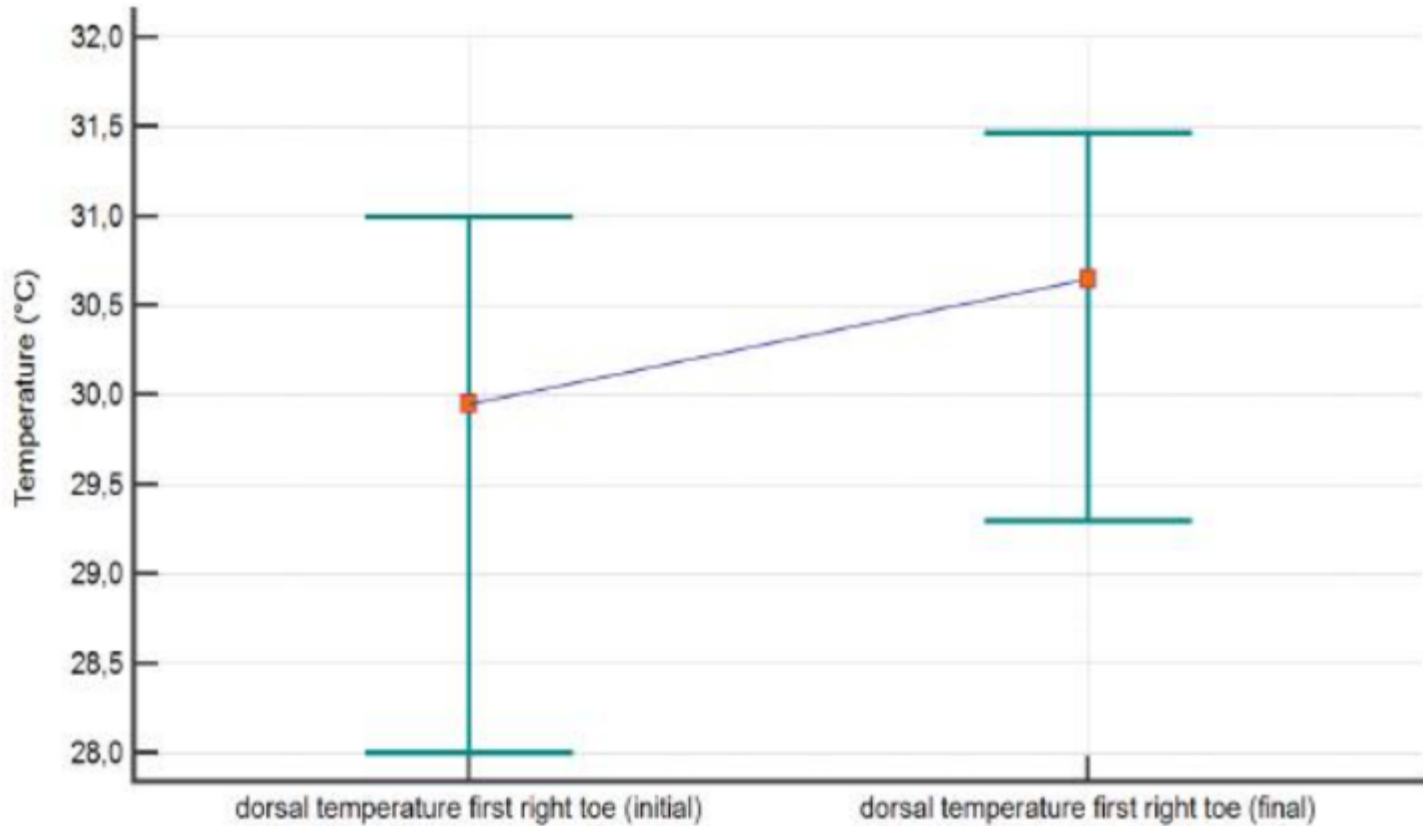
Initial temperature: 29.95 CI(28 to 31)
Final temperature: 30.65 CI (29.3 to 31.4)
p=0.045

Distance and time to Claudication using a treadmill at 3.5 miles per hour. 6 weeks

DISTANCE TO CLAUDICATION BEFORE AND AFTER TREATMENT

Initial Median 100 IC (50 to 200) - Final Median 535 IC (382,947 to 800)
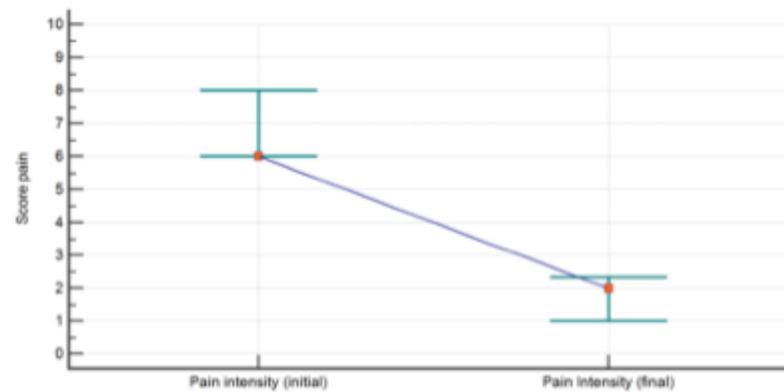
The difference was statistically significative

Wilcoxon test (paired samples) Two-tailed probability p<0,0001

Subjective Pain Sensation (6 weeks)

GRAPHIC THREE

SUBJETIVE PAIN INTENSITY SENSATION

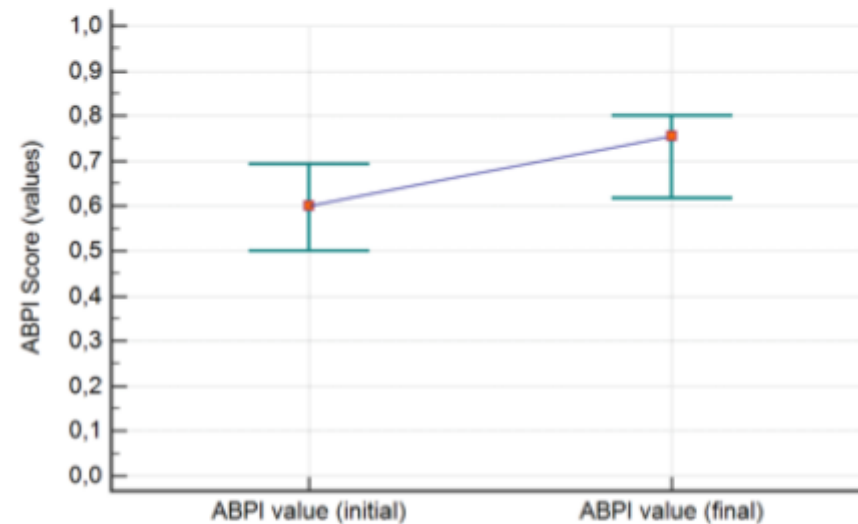It was done using median values and 95 % confidence intervals

Pain intensity (initial) Median 6 IC (6 to 8)

Pain intensity (final) Median 2 IC (1 to 2,341)   p=<0.0001

Ankle/Brachial Index. 6 weeks

ANKLE /BRACHIAL INDEX BEFORE AND AFTER TREATMENT

It was done using median values and 95 % confidence intervals
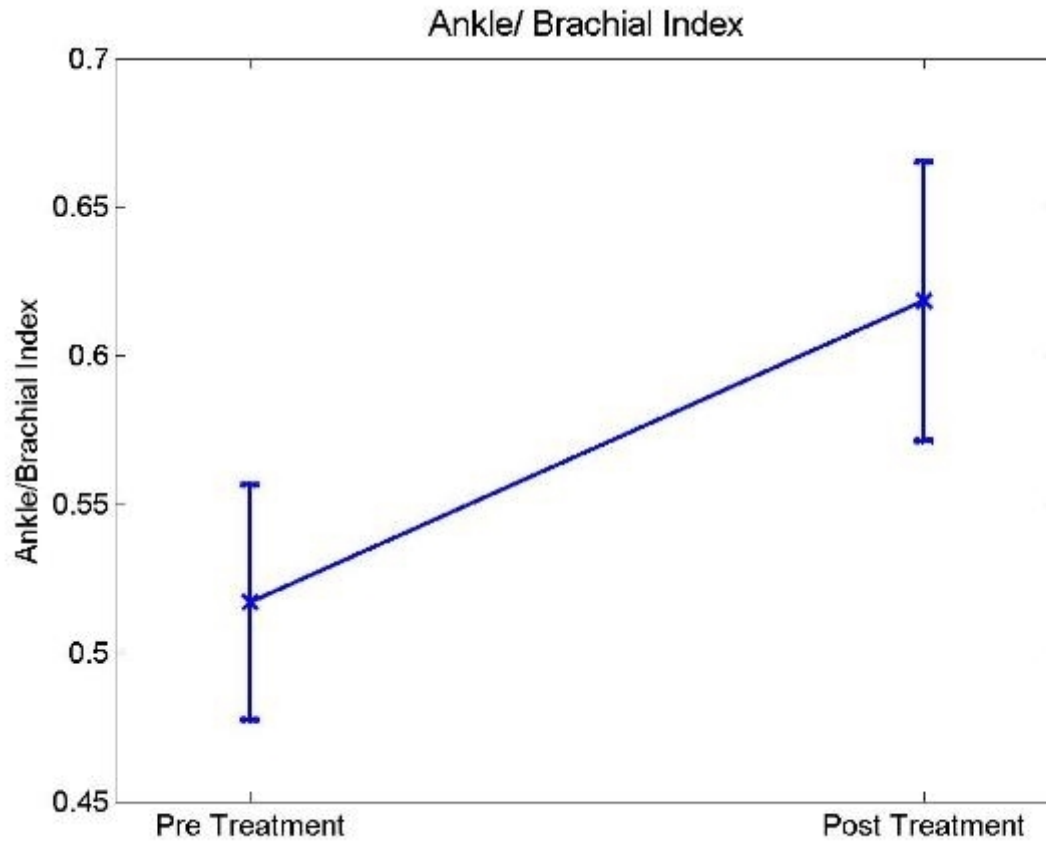

ANKLE /BRACHIAL INDEX BEFORE AND AFTER TREATMENT

BEFORE AND AFTER TREATMENT

Initial Median 0,6 IC (0,50 to 0,69) - Final Median 0,75 IC (0,62 to 0,80)
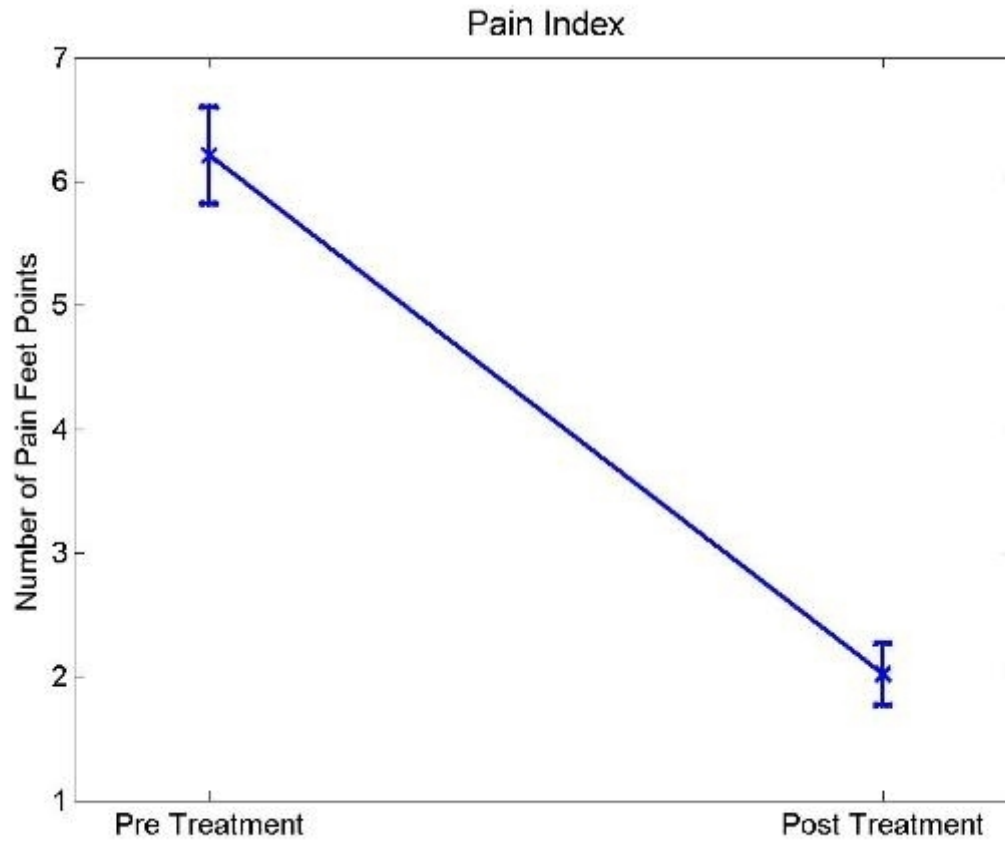
The difference was statistically significative

Wilcoxon test (paired samples) Two-tailed probability p<0,0001
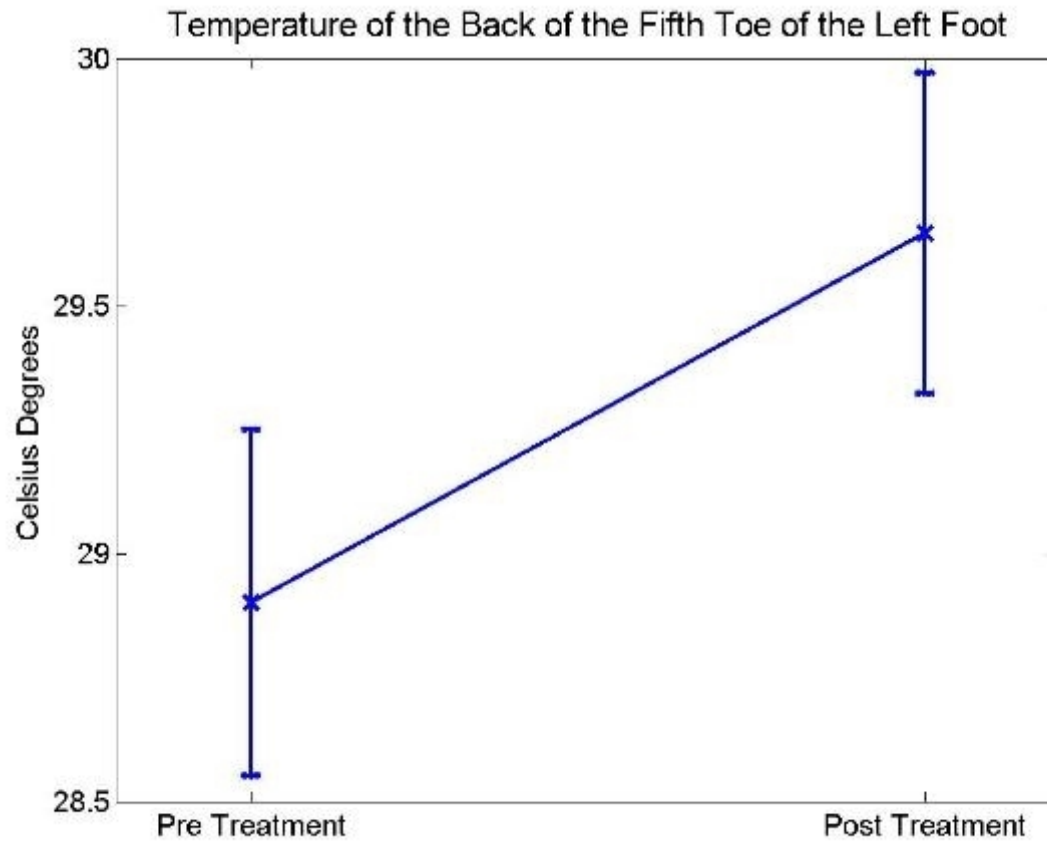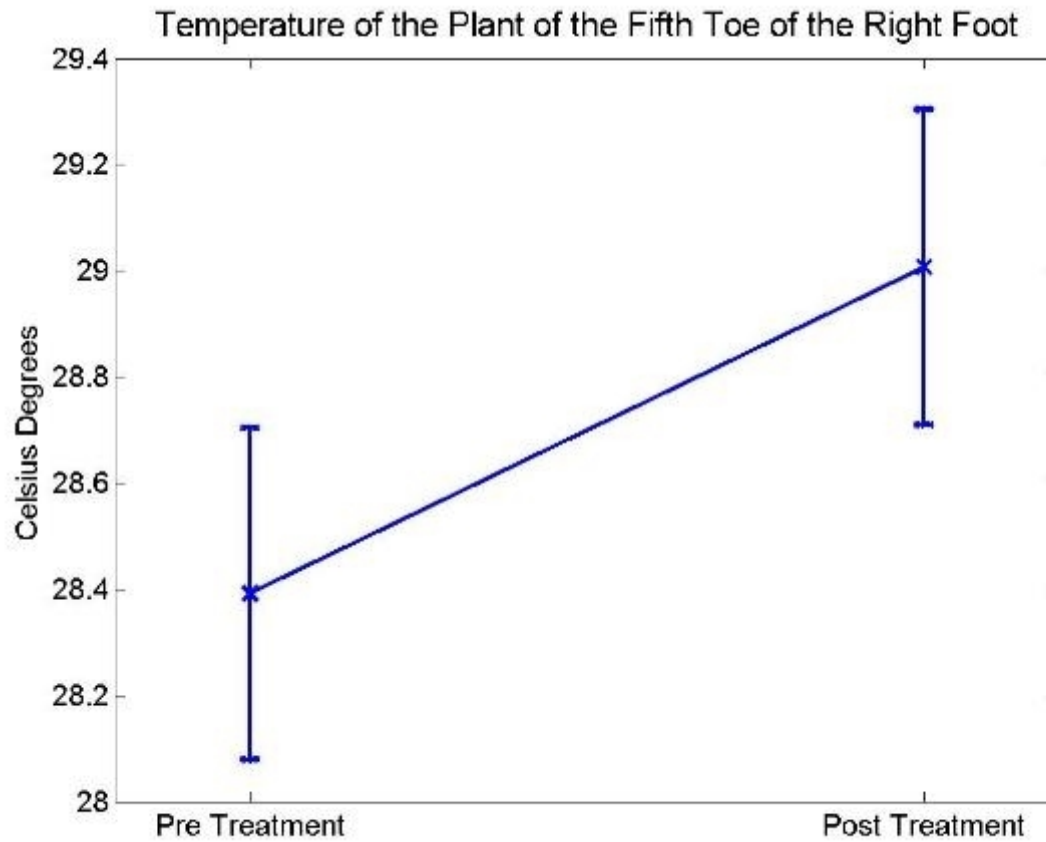
Ankle / Brachial Index Variations at 6 months

Pain Index
Variation at 6 months

Temperature of the Left Foot (6 Months)

Temperature of the Back of the Fifth Toe of the Left Foot

Temperature of the Right Foot (6 months)

Temperature of the Plant of the Fifth Toe of the Right Foot

Distance to Claudication (6 months)
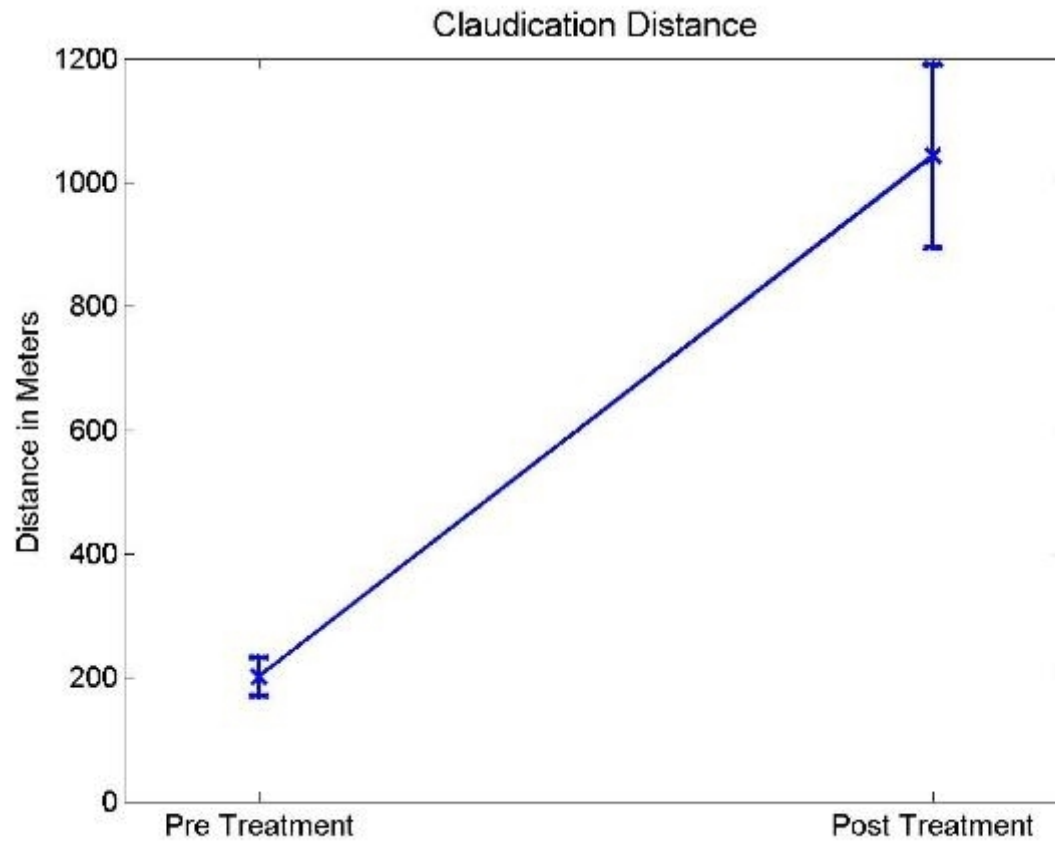
Discussion

Dehydration is common in elderly patients, one every ten admission to American hospitals are because dehydration.

Dehydration can occur because fluid losses or decreased intake.

Elderly people drink less fluids because the sensation of thirst decrease.

This decrease of thirst sensation can occur because depletion in dopamine level and increased level of plasma Atrial Natriuretic Peptide (ANP).

Discussion

The body water composition decreases from 60 to 55 % because of the decrease in muscles and an increase in fatty tissue, renal function is impaired with less capacity to concentrate, increasing urine formation. Kidneys are also less reactive to ADH and have a lower ability to regulate Sodium excretion. Lastly iatrogenic factors can aggravate dehydration (Laxatives, diuretics or angiotensin converting enzyme convertors).

Conclusions

- Most of elderly patients with disabling intermittent claudication or rest pain, were drinking a low volume of water (Median 1000 ml).

- All patients responded to an increase of fluid intake and oncotic pressure of plasma.

- Difference in pain sensation, ankle/brachial index and distance and time to claudication, comparing before treatment and after treatment were statistically significant.

- In the last 12 months our cases of angioplasty and/or stenting dropped almost 90%

Limitations

- Small number of patients

- Short follow-up

- No control group