

Effects of balloon angioplasty on symptoms in CCSVI-MS patients.

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Eight Years Between PTA results and Follow-Up in Multiple Sclerosis. A retrospective analysis and eventual (possible) predictive considerations.

Disclosure Statement

I here declare total absence of Any Sort of Interest Conflicts

either past or present regarding CCSVI or any other Topic here treated

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May symptoms of chronic cerebrospinal venous insufficiency be improved by venous angioplasty?

P.M.Bavera Veins and Lymphatics 2015; volume 4:5400

The aim of the study was to

collect results from **366** chronic cerebrospinal venous insufficiency (CCSVI) affected patients that were regularly Duplex controlled for 4 years (2010- 2014).

after having received vein angioplasty following diagnosis for CCSVI.

The patients were divided into three groups according to the attributed severity of the associated multiple sclerosis:



62 secondary progressive (17%): 37 (59.7%) females and 25 (40.3%) males; 40 primary progressive (11%): 22 (55%) females and 18 (45%) males.

A data base revealed eleven most frequent disturbs and symptoms, together with working capacities, and was kept up-to- date at every Duplex control aiming to establish a novel rapid CCSVI symptoms questionnaire assessment in 4 years follow up. The symptoms were: diplopia, fatigue, headache, upper limb numbness/mobility, lower limb numbness/mobility, thermic sensibility, bladder control, balance coordination, quality of sleep, vertigo, mind concentration.

The question is: What has happened to the 264 R-R Patients from then on? How are they still doing?

The answer isn't simple to give, since 2018 gave the lowest availability to be updated

Three successive Papers didn't help much either

1) Efficacy and Safety of Extracranial Vein Angioplasty in Multiple Sclerosis A Randomized Clinical Trial (see Editor's Comment)

Zamboni et Al. JAMA Neurology | Original Investigation

2) Extracranial venous angioplasty is ineffective to treat MS

Zivadinov et Al. NATURE REVIEWS **NEUROLOGY**

"A randomized, double-blind, sham-controlled trial, Brave Dreams, has shown

no clinical or radiological benefit of percutaneous transluminal angioplasty....

"These results finally settle the scientific debate over whether PTA can improve clinical, radiological and symptomatic outcomes in this patient population."

3) Safety and efficacy of venoplasty in MS A randomized, double-blind, sham-controlled, phase II trial

Traboulsee et Al. Neurology

"<u>Personnel at all sites underwent standardized training for ultrasound</u>, venography, and venoplasty procedures."

This takes us back to the initial Paper*:

On the basis of 264 relapse-remitting (RR) followed up between November 2010 and December 2014

- a) 248 (93.9%) were followed until December 2016 (16 went lost)
 - b) 190 (71.7%) were followed until <u>December 2017 (74 lost)</u>
 - c) 99 (37.5%) were followed until May 2019 (165 lost in total)

*May symptoms of chronic cerebrospinal venous insufficiency be improved by venous angioplasty?

Veins and Lymphatics 2015; volume 4:5400

a) 248/264 (93.9%) were followed until December 2016

At this time the Patients were all doing well and living a satisfying lifestyle 247/248 (99.6%) Good Duplex outflow.

Except one, 1/248 (0.4%), that had turned into a Secondary Progressive four years after the second PTA

b) 190/264 (71.7%) were followed until December 2017

Once again declared living a satisfying lifestyle and showed regular Duplex Jugular outflow 189/190 (99.4%)

Another Patient had a worsening of the MS disease and became a S-P after two PTA's (0.6%)

c) 99/264 (37.5%) were followed until May 2019 Most were still well (98.0%) with free J.V's

Two more had turned into Secondary Progressive 2/99 (2.0%) six years after previous, and third, PTA

The only possible conclusion **so far** is that between November 2010 and May 2019

4 certainly became Secondary Progressive (1.6%)

and <u>"potentially"</u> 260 remained R-R (98.4%)

with satisfying Jugular Vein outflow

But there also is an indirect and unexpected* Control Group

*Unexpected because it grew spontaneously, but very valuable

There is now a NEW Group to be considered.

Between November 2010 and December 2014

531 R-R Patients underwent to Duplex scanning and then never returned for controls

and so no follow-up was possible.

Between January 2016 and May 2019

164 (31%) of these Patients showed-up.

None of these ever underwent to PTA although their Duplex exam for CCSVI was positive the first time.

All these 164 Patients returned because they complained for worsening symptoms, secondary to their MS disease.

Limb mobility (upper and lower) and fatigue were above all the <u>main symptoms</u>, together with constant worsening of MRI.

16 (9.75%) had turned into Secondary Progressive and now needed sticks or crutches to walk outside their home.

For everybody (both Groups)

Duplex Imaging was carried out and then, compared to their previous exam

Results being quite surprizing..

IN BOTH GROUPS (Yes PTA / No PTA) left Internal Jugular vein confirmed a situation similar to the previous, most frequently with valve irregularities at the B-Cephalic Junction

The differences mainly occurred to the RIGHT SIDE IJV

with a tremendous narrowing at the J1-J2 segment and a bloating just above and principally seen

when sitting up (90°)

(a sort of hourglass effect)

In Between the two segments there was a significant Extrinsic Compression due to a muscle (omohyoid) that turned to be hypertrophic in presence of postural ambulation problems (the Turtle-Neck Position) also due to use of inevitable walking devices

So, summing the 20 R-R Patients (4+16) that became Secondary Progressive, 18 (90%)

showed significant worsening of the RIGHT Internal Jugular Vein and only 2 had bilateral outflow worsening.

These problems were all most evident in the sitting-up position (90°)

My series of Patients that were Duplex followed in 8 or more years showed

a significantly better life outlook

for those that had improved their jugular venous outflow AFTER PTA

It remains to be cleared which outflow method/material could be better

- PTA alone
- PTA + eventual stenting (when it will be available)
 - Open Surgical correction

(that I am now seeing quite frequently)

- Only Hemoreologic Drugs (hoping on collateral circuit)

I am also asking myself:

Why does the jugular venous outflow malfunction principally occur on the right side (in my series) once the disease becomes Progressive.

Is it a pure coincidence?

Is it a consequence to bad postural ambulation or Vice-Versa?

Could it be prognostic?

I here Conclude,

A POOR CEREBROVASCULAR OUTFLOW is an abnormality that can give consequences, it should be, when possible, safely corrected

Remember that carotid endarterectomy,

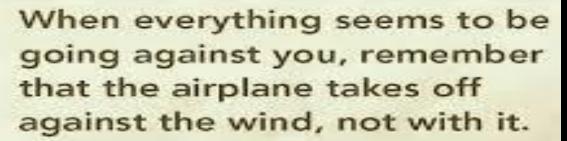
which now is a well-accepted common stroke prevention technique in a subset of patients,

was questioned as recently as 1984...

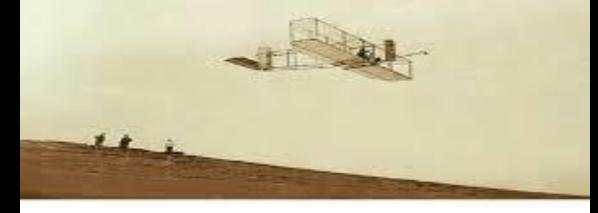
Barnett HJM, Plum F, Walton JN.

Carotid endarterectomy - an expression of concern.

Stroke 1984;15:941-43.



- Henry Ford



Thank You for your kind attention

