

## **THERAPEUTIC TRIAL OF A PERIPHERAL ANGIOPROTECTOR, Endotelon**

Flavanoid oligomers, extracted from grapes, are the principal ingredient of the microangioprotector Endotelon. We tested this product on 78 patients showing signs of an increase in vascular fragility and capillary permeability. Only those patients showing an increase in indications of capillary fragility before the test were included in the study. The variations in these signs (measured using the Parrot angiosterrrometer) gave us an objective criteria of evaluation of the action of Endotelon in the treatment of peripheral microangiopathy.

Endotelon comes in the form of a pill and has the following formula: Grape oligomer (O.P.C.).

### **SIGNS**

The 78 observations were broken down thusly:

- Varicose veins – 4
- Varicosity and telangiectasy – 15
- Post phlebitis disease – 3
- Leg ulcers – 36
- Vascular fragility with Bateman bruises and ecchymosis – 12
- Blotches and rosacea – 3
- Others – 5

### **DOSAGE**

The average dosage was 3 pills of 50mg a day. The length of the study was from 15 days to 3 months.

### **EVALUATION OF THE RESULTS**

The results were evaluated:

- Clinical criteria
  - Modifications in the objective signs
  - Variations in the functional signs

After measuring the signs of capillary fragility:

The signs of vascular fragility were measured by using the Parrot angiosterrrometer with the principle being to provoke an experimental purpura through depression using a suction cup attached to a manometer. In the presternal region we caused a depression of at least 20cm of mercury, then moving the suction cup we create another depression of 30cm and less than 40cm of mercury for the length of one minute. Using a jeweler's magnifying glass we count the number of red spots and used the following scale:

- Less than 3 red spots: 0
- Between 3 and 5 : +
- Between 6 and 10: ++
- More than 10: +++

- Ecchymosis: ++++

The Vascular Fragility Indicator (V.F.I.) is calculated by multiplying by a coefficient the number of crosses (+) for each depression:

- Less than 40cm of mercury: 5
- Less than 30cm of mercury: 10
- Less than 20cm of mercury: 15
- Less than 10cm of mercury: 20

and then totaling the partial results. Capillary resistance is considered normal when the V.F.I. is between 0 and 10.

### **Before Endotelon Treatment**

The V.F.I. is increased in all the observations (this was one of the criteria in choosing the patients).

### **After Endotelon Treatment**

The V.F.I. is considered:

- Normalized between 0 and 10
- Unchanged: equal to the V.F.I. before treatment or a variation of 5 points.
- Increased: more than 5 points compared to the initial figure.
- Improved: lowered more than 5 points and less than 45 points.
- Greatly improved: lowered more than 45 points or more.

The clinical results and the modifications of the V.F.I. are not always in the same sense but for each patient we endeavored to give a global evaluation. In the analysis of the results we studied on one hand the entire study and on the other hand the effect of Endotelon on V.F.I.

## **Tolerance**

Tolerance was studied under a clinical surveillance. What's more in twelve of the patients a biological assessment (numeration and blood formula, sedimentation speed, blood urea, glycemia, transaminasis) was done before treatment and after 15 days of Endotelon.

## **Results of Using Endotelon**

The results can be expressed like this:

Global evaluation, taking into account the clinical modifications under Endotelon and the variations in the V.F.I. Therefore, out of 78 patients treated we obtained the following:

- 22 very good results
- 32 good results
- 21 average results
- 3 no results

Isolated results on the V.F.I. Of the 78 patients, the V.F.I. was:

- normalized in 24 cases
- greatly improved in 20 cases
- improved in 18 cases
- unchanged in 13 cases
- increased in 3 cases

Endotelon therefore improved capillary resistance in 62 of the 78 cases. The correction of vascular fragility was normalized in 24 cases. These positive results in 79.4% of the cases allow us to consider Endotelon as an excellent microvascular protector.

### **Analysis of the Results of the Diverse Indications**

#### R E S U L T S

Indications	Patients	Very Good	Good	Average	None
Varicose Veins	4	1	1	2	
Varicosities	15	8	5	2	
Post Phlebitis	3		3		
Leg Ulcers	36	7	16	12	1
Bateman Bruises	12	4	5	3	
Blotchy Rosacea	3	1	2		
Diverse	5	1		2	2
Total	78	22	32	21	3

Remember that for this study on the effects of Endotelon the patients who were chosen:

- were stricken with an ailment relevant to an angioprotector
- all showed a vascular fragility in order to have a concept of clinical evolution, and a criteria of measurable therapeutic efficiency.

This would explain the distribution of the patients: Relatively few of the varicose, much more with varicose veins, Bateman bruises, and especially those with leg ulcers.

#### **Varicose Veins**

Amongst the four patients with varicose veins we obtained the following:

- 1 very good result
- 1 good result
- 2 average results

In the second observation the results were considered average despite a very good efficiency on the clinical plan because of the non variation of the V.F.I.

Of course, Endotelon as with any other angioprotector cannot pretend to replace the active therapy of treating varicose veins with surgery or scleroses. But it did appear to

us to present a very satisfying efficiency on the painful functional phenomenon as well as permitting a better tolerance of the scleroses.

### **Varicosity and Telangiectases**

Of the 15 patients afflicted with varicosity the results of Endotelon are very interesting. In effect, we obtained:

- 8 very good results
- 5 good results
- 2 average results

What is more, Endotelon obtained very good results on the functional plan. The fine varicosities were often more painful than the varicose veins, more voluminous, especially before menstruation or hot flashes. Endotelon especially allowed these patients with greatly increased V.F.I. and with a tendency towards hematomas to get good esthetic results without inflammatory reactions.

### **Post Phlebitis**

Of the 3 patients afflicted with post phlebitis the results in all three cases were good. What is more, with Endotelon a rapid sedation of pain, a decrease of the oedemas and inflammation and a correction of the vascular fragility.

### **Leg Ulcers**

Of the 36 patients we obtained the following global results:

- 7 very good results
- 16 good results
- 12 average results
- 1 no result

But the quality of the results varies according to the cause of the ulcer as is shown in the table below.

#### RESULTS

Etiology of the leg ulcer	# of cases	Very good	Good	Average	Nothing
Varicose	2	1	1		
Post Phlebitis	11	2	7	2	
Arteritis	2			2	
Angio-capillarity	17	3	6	7	1
Mixed	4	1	2	1	

It's in observing varicose ulcers and post phlebitis ulcers that Endotelon, associated with an elastic application for scleroses, proved itself to be the most efficient in obtaining a rapid disappearing of pain and healing in the shortest amount of time.

The two patients with arteritis, aged 90 and 76, the healing was slower and the results were shown to be average.

In the ulcers from angiocapillarity, occurring more and more frequently in elderly people along with arteriosclerosis, the results of using Endotelon appeared to especially interesting. At first glance the results were not as good as in those with varicose ulcers or post phlebitis. But you have to take into consideration the very painful and desperately long habitual evolution of these ulcers in which healing is always difficult.

The fact that we obtained 3 very good results and 6 good results out of 17 patients appears to us to be very favorable. Endotelon would appear to be well placed in the treatment of ulcers caused by angiocapillarity.

The results were equally satisfying in use for mixed ulcers associated with a angiocapillarity from other causes.

### **Bateman Bruises and Ecchymosis**

In the 12 cases of capillary fragility with Bateman bruises and ecchymosis the results were as follows:

- 4 very good
- 5 good
- 3 average

The efficiency of Endotelon is therefore found to be very satisfying in this use.

### **Blotches and Rosacea**

In the 3 cases of blotches and rosacea the results were:

- 1 very good result
- 2 good results

The prescription of Endotelon during this period of treatment by electrocoagulation helped ease this therapy and there was less bleeding. Using Endotelon also helped the esthetic results.

### **Diverse**

The last five observations gave us disparate results.

- One very good result was obtained in the one case of angiocapillarity with microthrombosis. The lesion did not come to a head as we'd worried it would in the ulceration and the pain quickly went away. The principle of the indication is the same as in the ulcers with angiocapillarity.
- In 3 vascular bruises the exact etiology was not readily evident. We obtained:
  - 2 average results
  - 1 with no result

The pathogen of these vascular bruises is often complex and here Endotelon really only plays an adjuvant role.

Finally, one "no result" in an indication limits the vascular protectors.

## **TOLERANCE**

Tolerance was excellent on the clinical plan, notably from a digestive point of view with doses varying between 100 and 200 mg a day.

A biological assessment was done on 12 hospitalized patients before and after treatment. This assessment brought forth:

- Numeration and blood formula
- Speed of sedimentation
- Urea
- Glycemia
- Transaminasis

These biological constants did not vary in any significant fashion during the Endotelon treatment.

## **CONCLUSIONS**

We used Endotelon in 78 patients suffering from effects of capillary fragility. The results obtained were very favorable:

- 22 very good results
- 32 good results
- 21 average results
- 3 no results

The fragility index of these patients was:

- Normalized in 24 cases
- Very improved in 20 cases
- Improved in 13 cases
- Unchanged in 13 cases
- Increased in 3 cases

Endotelon therefore corrected in a very efficient fashion capillary fragility in 62 out of 78 patients.

Tolerance for Endotelon was excellent on both the clinical and biological plans. In conclusion Endotelon appears to us to be a very efficient angioprotector especially in treating:

- Varicose veins
- Varicosities and telangiectasies
- Post phlebitis disease
- Ulcers of the leg
- Capillary fragility with Bateman bruises and ecchymosis
- Blotching and rosacea during electrocoagulation treatment

NOTE: Endotelon is a French drug made from OPC extracted from Grape Seeds