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PERCUTANEOUS TRANSLUMINAL RENAL ANGIOPLASTY – A MULTICENTRE STUDY OF THE LONG TERM RESULTS

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Abstract – To assess the long-term clinical effect of percutaneous transluminal angioplasty of the renal artery (PTRA), patients with clinical examinations and laboratory tests performed before PTRA and within a minimum of 3 months following the investigation were considered eligible for inclusion. Patients with fibromuscular disease of the main and/or branch renal arteries were the most suitable candidates for PTRA, because two thirds of them showed a blood pressure benefit at 5-year follow up. These results are similar to those achieved in the group of patients with atheromatous disease. Authors discuss the clinical and laboratory characteristics and radiočlogic aspects of PTRA, the technical standard of the procedure, complications and number of redilatations.

UDC: 616.136.7.272-089.844

Key words: renal artery obstruction, angioplasty transluminal

Orig sci paper

Radiol Iugosl 1990; 24: 137-45.

Introduction – Percutaneous renal angioplasty (PTRA) has become an established interventional method used in the treatment of renal artery stenosis. While in stenoses caused by fibromuscular dysplasia, it is the method of first choice, there has not been unanimity redgarding its superiority in cases of stenoses of atherosclerotic origin. Substantial improvement of renovascular hypertension following PTRA has been reported in fibromuscular stenoses rather than in atherosclerotic stenoses.

Doubtless, any further piece of experience, especially that gained in a large group of patinets followed up for a rather long period of time after PTRA, helps to build the body of hard evidence available. It was for this reason that we decided to conduct a multicentre study designed to assess retrospectively the long-term effect of PTRA on blood pressure in atherosclerotic, fibromuscular and other types of lesions, and to suggest whether the long-term effect can be predicted on the basis of the angiographic finding obtained immediately after PTRA.

Patients and methods – The project was joined by the following centres:

1. Department of Radiology; Institute for Clinical and Experimental Medicine (A. Belan), Prague, Czechoslovakia
2. All-Union Scientific Centre of Surgery; Academy of Medical Sciences (I. Kh. Rabkin), Moscow, Soviet Union
3. Institute of Rentgenology University Medical Center (D. Pavčnik), Ljubljana, Yugoslavia
4. Municipal Hospital Friedrichshein, Department of Cardiovascular Diagnosis (J. H. A. Muller), Berlin, German Democratic Republic
5. Clinic of Radiology (L. Horvath), Pecs, Hungary
6. Institute of Cardiovascular Surgery of A. N. Bakulev (I. Petrosyan), Moscow, Soviet Union

The study was coordinated by the Department of Radiology of the Institute for Clinical and Experimental medicine in Prague where a questionnaire for retrospective data collection was drawn and distributed to each participating centre. The questionnaire was to be filled for each patient undergoing PTRA before 31 December, 1987. The contribution of each centre to the basic group of patients is shown in Table 1.

Twenty-three patients after PTA of the renal graft artery were excluded from the study in order to be assesed separately. The remaining

Received: March 3, 1990 – Accepted: April 10, 1990

Table 1 – Contribution of each centre to the basic group

of the renal artery	No. of all pts after PTA entire group	Percentage of the of the renal graft artery	No. of pts after PTA
1. Prague	134	30.5	18
2. Moscow R.	118	26.9	1
3. Ljubljana	91	20.7	3
4. Berlin	34	7.7	1
5. Pecs	32	7.3	0
6. Moscow P.	30	6.8	0
Total	439		23

416 patients were divided into three groups by the etiology of the stenosis:

I. ATHERO (atherosclerosis), n = 261,
II. FMD (fibromuscular dysplasia), n = 109,
III. OTHERS (mostly vascular lesions in arteritis and other systemic diseases), n = 46.

In some cases, the etiology of stenosis was established by histological examination of the artery after its surgical reconstruction, nephrectomy, or at autopsy.

The clinical and laboratory characteristics of the patient group before PTRA are shown in Table 2.

Table 2 – Clinico-laboratory characteristics of the group of patients before PTRA

		I. ATHERO n = 261		II. FMD n = 109		III. OTHERS n = 46	
Mean age (years)		n = 260 50.4±7.5		n = 107 34.5±9.9		n = 45 32.7±11.3	
Sex male		196	75.1%	38	34.9%	28	60.9%
female		65	24.9%	71	65.1%	18	39.1%
Extrarenal manifestations of atherosclerosis		131	50%	10	10%	5	11%
Primary renal disease		38	14.5%	19	18%	7	15.5%
Systemic disease (incl. diabetes mellitus)		19	7%	2	2%	5	11%
WHO class of hypertension	I	27	10.8%	32	29.6%	15	32%
	II	192	77.1%	68	63%	29	64%
	III	30	12%	8	7.4%	2	4%
Plasma creatinine (umol/l)		n = 199 127.2±75.6 (40–764)		n = 94 91.8±26.0 (46–198)		n = 27 110.6±20.1 (88–190)	
Blood pressure (mmHg)	systole	n = 255 197±31		n = 108 182±30		n = 45 190±29	
	diastole	114±17		113±15		114±16	
	mean	142±20		136±19		140±18	
Antihypertensive therapy							
– none		11	4.4%	4	3.8%	5	11.1%
– 1–3 hypotensives		202	80.8%	92	86.8%	36	80.0%
– > 3 hypotensives		37	14.8%	10	9.4%	4	8.9%
Indications for PIRA							
– hypertension		223	87.7%	99	94.3%	41	89.1%
– hypertension with deteriorated function		31	12.2%	6	5.7%	5	10.9%

As expected, the mean age was markedly higher in Group I (ATHERO), with men prevailing and extrarenal complications (ischemic heart disease, atherosclerosis of the lower extremities, stroke) present more often than in the other groups. In Group II (FMD), women prevailed and the mean age was lower. There was no difference between the groups as to other parameters (presence of primary renal disease, systemic disease, WHO classification of hypertension, plasma creatinine level, blood pressure before PTRA and the number of hypotensive drugs used). The higher incidence of systemic diseases in Group I was due to the more frequent incidence of diabetes.

The radiologic characteristics are given in Table 3.

Complications requiring surgery were found in 12 patients. Nephrectomy had to be performed in three cases and aortorenal bypass in nine.

The angiographic finding of the renal artery immediately after PTA was assessed as »normalized« in disappeared stenoses, »improved« in cases of stenoses smaller than before the procedure, and »not improved« in persisting stenoses of the same extent.

From the basic group (n = 416), a total of 154 patients (37%) undergoing successful PTRA without redilatation, with clinical examination and laboratory tests done before PTRA and followed up for a minimum of 90 days since dilatation, were selected to evaluate the effect of PTRA on blood pressure and renal function.

The following criteria were chosen:

Table 3 – Radiologic characteristics of the group

	I. ATHERO n = 261		II. FMD n = 109		III. OTHERS n = 46	
Side of stenosis						
* right	90	34.4	61	55.9	22	47.8
* left	125	47.9	37	33.9	12	26.1
* right + left	46	17.6	11	10.1	12	26.1
Number of dilated arteries one	207	79.6	96	89.7	32	69.6
two	50	19.2	10	9.3	14	30.4
three	3	1.2	1	1.0	0	
Technical failure	16	6.1	9	8.2	10	21.7
Complications of PTRA	23	8.8	17	15.6	5	10.9
Angiographic finding after PTRA						
* normalization	127	48.8	42	38.5	21	46.7
* improved	119	45.8	56	51.4	18	40.0
* unchanged	14	5.4	11	10.1	6	13.3
Number of redilations	27	10.3	12	11.0	1	2.2

Patients in Groups I and III showed more frequent bilateral stenosis. The number of dilated arteries in the ATHERO and OTHERS groups is likewise higher than in that with FMD stenoses. In atherosclerotic stenoses neither information on the type of stenosis nor records on the angiographic finding of the peripheral arterial bed are available.

Post-PTRA complications, regardless the etiology of stenosis, were observed in 10.8% of patients. Half of them were minor complications, i.e., renal artery spasm, and complications at the puncture site, with the remaining 50% of complications made up by dissections, embolization, perforation or rupture of the artery, occllusions and an immediate decrease in renal function.

Renal function was regarded as unchanged if plasma creatinine level had been within normal limits (i.e., up to 125 umol/l) also before PTRA, or when the change, in patients with initial levels over 125 umol/l, did not exceed 20% of the initial value after PTRA. Our definition of functional deterioration included cases with normal ilnitial creatinine levels and follow-up levels exceeding 125 umol/l, or a rise from values over 125 umol/l by more than 20%. An improvement in function was registered if creatinine decreased from levels over 125 umol/l to below 125 umol/l, or by more than 20% from levels initially higher than 125 umol/l.

Blood pressure was considered normal if the value of systolic pressure was lower than 165

mmHg, that of diastolic pressure lower than 95 mmHg, and the value of mean pressure below 110 mmHg. Our definition of improvement was a decrease of elevated values to normal level, or a decrease of elevated values by at least 15% of the initial value.

Results – The values of plasma creatinine and blood pressure before and after a minimum of 90 days following PTRA in our group of 154 patients are shown in Table 4.

Changes in renal function before and after PTRA were assessed by changes in plasma creatinine levels. In Group I (ATHERO) improvement and deterioration were noted in five cases each. There was no change in the remaining patients. Improvement and deterioration were observed in one case each in Group II (FMD)

Table 4 – Plasma creatinine and blood pressure values in a group of 154 patients examined before PTRA and after a minimum od 90 days later

	I. ATHERO n = 97		II. FMD n = 44		III. OTHERS n = 13	
	before	after	before	after	before	after
	n = 64	53	n = 39	35	n = 6	6
Plasma creatinine	121.9	123.3	93.9	91.8	129.1	106.2
(umol/l)	± 52.8	62.9	27.1	25.5	35.0	14.2
Blood pressure	n = 94		n = 44		n = 11	
systole	190.6	151.6	177.8	143.7	177.7	136.1
	± 33.4	19.8	33.9	15.6	38.3	41.4
diastole	110.1	93.3	108.9	91.7	107.5	92.7
	± 16.4	10.1	15.5	9.3	16.0	14.9
mean	136.9	113.0	131.9	109.0	133.0	110.6
	± 20.7	12.0	20.6	10.4	20.2	21.4

Table 5

1. Follow–up > months after PTRA (n = 149)

Mean BP	ATHERO		FMD		OTHERS		TOTAL	
	n	%	n	%	n	%	n	%
Improved	67	71.3	28	63.6	9	81.8	104	67.8
Not improved	27	27.7	16	36.4	2	18.2	45	30.2
Total	94		44		11		149	

2. Follow up > 12 months after PTRA (n = 99)

Mean BP	ATHERO		FMD		OTHERS		TOTAL	
	n	%	n	%	n	%	n	%
Improved	51	75.0	13	52.0	6	100.0	70	70.1
Not improved	17	25.0	12	48.0	0	0	29	29.3
Total	68		25		6		99	

3. Followûp > months after PTRA (n = 66)

Mean BP	ATHERO		FMD		OTHERS		TOTAL	
	n	%	n	%	n	%	n	%
Improved	30	69.8	9	53.0	6	100.0	45	68.2
Not improved	13	30.2	8	47.0	0	0	21	31.8
Total	43		17		6		66	

4. Followûp > 60 months after PTRA (n = 23)

Mean BP	ATHERO		FMD		OTHERS		TOTAL	
	n	%	n	%	n	%	n	%
Improved	14	82.4	3	75.0	2	100.0	19	82.6
Not improved	3	17.6	1	25.0	0	0	4	17.4
Total	17		4		2		23	

patients. Since plasma creatinine was determined in six patients of Group III (OTHERS) only, the changes were not assessed.

The long-term effect of PTRA on blood pressure was evaluated at three months (n = 149), at 12 months (n = 99), at 24 months (n= 66) and at 60 months (n = 23). The mean follow-up period (n = 154) was 31 ± 26.8 months (range, 3.3 – 92.8 months). Improvement of mean blood pressure is shown in Table 5.

The cumulative curves of improvement of blood pressure after PTRA according to the etiology of stenosis do not differ statistically over a five-year follow-up period (Fig. 1).

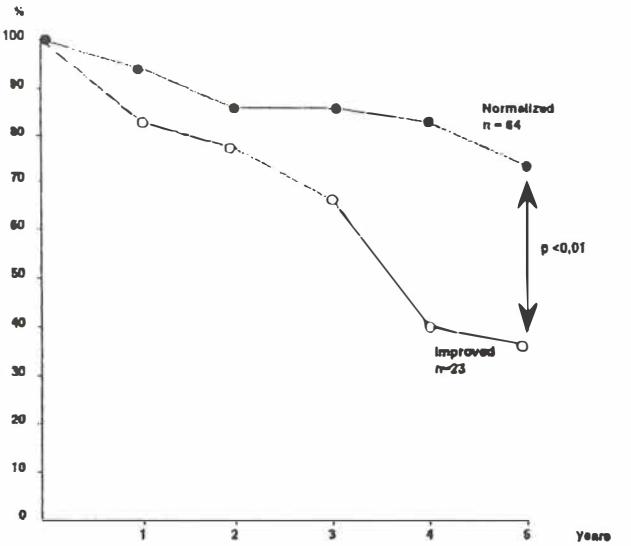

Fig. 1 – The cumulative curves of improvement of blood pressure after PTRA according to the etiology of the stenosis.

Three and more months after PTRA, mean blood pressure was improved in 104 patients (67.8%). The proportion of »improvement« in each group by the etiology of stenosis is shown in Table 6.

Both in the ATHERO and FMD groups, while the mean pressure of most patients was within normal values, they had to continue receiving hypotensives. The difference was Group II which comprised a substantially higher proportion of

Table 6 – Improvement of hypertension after PTRA

Blood pressure improvement > months after PTRA	ATHERO n = 67		FMD n = 28		OTHERS n = 9	
Improvement but mean BP > 110 mmHg thereafter	23	34.3%	3	10.7%	2	22.2%
Mean BP > mmHg with hypotensives	29	43.3%	14	50.0%	3	33.3%
Mean BP > 110 mmHg without hypotensives	15	22.4%	11	39.3%	4	44.5%

normotensives not taking hypotensive drugs (39.3% vs. 22.4%) and, on the contrary, the percentage of those remaining hypertensive following PTRA was considerably lower (10.7% vs. 34.3%). Group III could not be evaluated because of the small number of followed patients.

Comparison of patients who, while not taking hypotensive drugs, were normotensive at three months after PTRA (n = 30) with other patients on follow-up (n = 124) revealed that all the former had significantly lower mean blood pressure before PTRA (127 ± 10 vs. 137 ± 22 mmHG), and the WHO classification of their hypertension was likewise lower (Stage I hypertension in 57%, Stage III hypertension in 0%).

The therapeutic protocol in patients whose pressure remained unchanged three months after PTRA (n = 45, i.e., 30.2%) did not differ before and after PTRA, i. e., they received the same number of hypotensive drugs.

The correlation between the post – PTRA angiographic finding and the effect of the procedure is shown in Table 7. The options listed in the questionnaire regarding the post – PTRA angiographic finding on the renal artery comprised »normalized«, »improved« and »unchanged«.

The number of patinets with prolonged blood pressure improvement is substantially higher in the group with a »normalized« angiographic finding than in the group whose finding was »improved« only. The group with an »unchanged« angiographic finding was not evaluated owing to the small number of patients.

The cumulative curves of blood pressure improvement according to the post – PTRA angiographic finding of the artery irrespective of the etiology is shown in Fig. 2. The difference in the effect on blood pressure in normalized vs. improved findings is statistically significant.

Table 7

1. Follow–up at ≤ 3 months after PTRA (n = 149)

	Angiographic finding on the reanl artery after PTRA					
	Normalized		Improved		Not improved	
	n = 64	43.0%	n = 83	55.7%	n = 1	0.7%
Mean BP improved	54	84.5	49	59.0	1	50.0
Mean BP not improved	10	15.5	34	41.0	1	50.0

2. Follow-up at > 12 months after PTRA (n = 99)

	Angiographic finding on the renal artery after PTRA					
	Normalized		Improved		Not improved	
	n =42	42.4%	n = 56	56.6%	n = 1	1.0%
Mean BP improved	35	83.5	34	60.7	1	100.0
Mean BP not improved	7	16.5	22	39.3	0	0.0

3. Follow-up at > 24 months after PTRA (n = 66)

	Angiographic finding on the renal artery after PTRA					
	Normalized		Improved		Not improved	
	n = 27	40.9%	n = 38	57.6%	n = 1	1.5%
Mean BP improved	23	85.2	21	55.3	1	100.0
Mean BP not improved	4	14.8	17	44.7	0	0.8

4. Follow-up at > 60 months after PTRA (n = 23)

	Angiographic finding on the renal artery after PTRA					
	Normalized		Improved		Not improved	
	n = 14	60.9%	n = 8	34.8%	n = 1	23.0%
Mean BP improved	13	92.9	5	62.5	1	100.0
Mean BP not improved	1	7.1	3	37.5	0	0.0

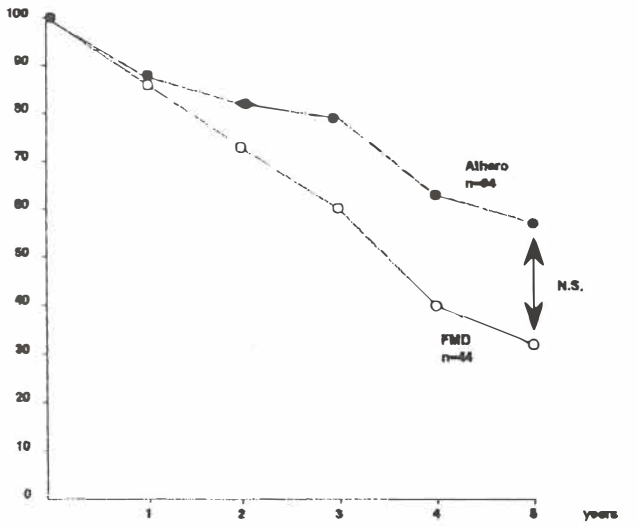

Fig. 2 – Cumulative curves of blood pressure improvement according to post–PTRA angiographe finding of the artery.

The long-term effect of redilatations could not be assessed in our group. Out of a total of 40 redilatation procedures, no data on blood pressure are available in 19 procedures and technical failures, i.e. renal graft recipient or an extremely short follow-up period, were involved in eight more cases. Of the remaining 13 redilatation procedures assessed at 3 months since the intervention, blood pressure was improved in six patients (all to normotension, one without the need for hypotensive drugs), and remained unaltered in seven subjects.

Discussion – Retrospective evaluation of PTRA and its long-term effect, especially if designed as a multicentric study, usually involves some pitfalls. The participating centres have different criteria for patient selection, a different technique of the procedure, assessment of complications and different regimens and methods of subsequent treatment and follow-up.

Regarding the clinical characteristics of our group (Table 2), we believe it is consistent with those reported in recent literature (1-7,8). Some data important for the evalulation of the long-term effect of PTRA, e.g., duration of hypertension before radiological procedure, more detailed specification and comparison of hypotensive therapy before and after PTRA, etc., are also missing in our case. It is a pity that as little as 37% of patients remained on long-term follow-up.

Radiological determination of the etiology of the stenosis may be likewise difficult. Considering the fact that the patient group was set up over a period of several years in six centres, it could not be assumed that the technique of PTRA in all patients was identical. That is why the initial success rate, which, in turn, as shown later, may play a major role in the evaluation of the long-term success rate, could not be analysed (1, 9). If we compare the initial success rate of PTRA (regardless the etiology) in our group with the summary published recently by Becker et al. (10), our group shows a very good initial technical success rate. Also the number of complications (approx. 10%), half of which represents minor complications, is consistent with data reported by other authors (3, 11, 12).

The indication for PTRA was hypertension in most of the patients enrolled into our study. Only a small proportion of Group I (ATHERO) patients (n = 31, i.e., 12.2%) and six patients (57%) in Group II (FMD) were considered for PTRA because of impaired renal function. One could not make any authoritative conclusions as to whether the cause of decreased renal function was invariably renal artery stenosis alone, or whether other factors were also involved (13). Moreover, the levels of plasma cratinine at the required intervals were not always available in this small

group either. The mean values of plasma creatinine before PTRA and at three months after PTRA were within normal limits in all three groups and did not change during follow-up.

Today, there is no doubt that PTRA has become an established technique for the treatment of renovascular hypertension and its results are comparable with those of surgical treatment (8, 14, 15, 16). The technique of PTRA and technology are being constantly refined (1, 17). Long term improvement of blood pressure and the percentage of cured patients (normotensives not requiring hypotensive therapy) are reportedly higher in Group II (FMD) (2-4, 6, 7, 8, 12, 14) than in group I (ATHERO). Significant imrpovement of systolic, diastolic and mean pressure after PTRA irrespective of the etiology of stenosis was found in 68% of our patients on long-term follow-up. Provided our criterion of clinical effect was a 15% decrease in mean blood pressure, or a decrease in mean blood pressure below 110 mmHg, the percentage of improved patients was higher in Group I (ATHERO), but the cumulative curves of improvement did not differ statistically (Table 5, Graph 1). However, the number of Group II (FMD) patients with pressure normalization was twice as high as that in Group I and, compared with Group I (ATHERO), only a third of FMD and, compared with Group I (ATHERO), only a third of FMD patients remained hypertensive, even though improved if assessed by our criteria (Table 6). We are not the first to make such an observation. Kuhlman et. al. (5) reported improvement in blood pressure at 21.6 months after PTRA in 48% of patients with atherosclerotic stenosis, and in as little as 32% of patients with fibromuscular stenosis, even though the percentage of normalized patients was higher in the FMD than in the ATHERO group (50.0 vs. 29.0%). It is implied that the etiology of stenosis, as established by angiography, is not neccessarily the basic factor determining the long-term effect of PTRA. Moreover, we are unable to make any conclusions regarding the duration of hypertension before PTRA, nor any other factors that might possibly play a major role. The results of our multicentric study in the ATHERO group were primarily attributable to the extremely good data obtained from the centres headed by Prof. Rabkin from Moscow and Dr. Horvat from Pecs.

The angiographic finding after PTRA has turned out to be a significant factor for the prediction of the long-term clinical effect of the procedure. Whereas in the case without residual stenosis (and a pressure gradient no longer persisted) the finding was assessed as »normalized«, patients with residual stenoses and residual pressure gradient were considered »improved«. Regardless the etiology of stenosis, the group with a »normalized« finding of the renal artery showed an effect »improved« finding, and the effect persisted for a long period of time (Table 7). The cumulative curve of blood pressure improvement is significantly better in the group of »normalized« stenoses (Fig. 2). Since no angiographic follow-up in patients after PTRA has been performed, we are unable to provide data on the incidence of restenoses neither can we assess the potential value of subsequent antiaggregation or anticoagulation therapy.

PTRA is an effective method for the treatment of renovascular hypertension. It is associated with a high technical success rate and a low rate of serious complications.

While, almost as a rule, the improvement of blood pressure in atherosclerotic stenoses is only partial and it is usually necessary to continue hypotensive therapy, in fibromuscular stenoses, normotension is rather often attained without further drug administration. A decrease in blood pressure found at three months after PTRA suggests permanent improvement in most cases.

The etiology of the stenosis, as established by angiography is not necessarily the main factor determining the long-term clinical effect. Another important predictor of long-term improvement seems to be the angiographic finding of the renal artery immediately after angioplasty.

Povzetek

MULTICENTIRIČNA ŠTUDIJA PERKUTANE TRANSLUMINALNE ANGIOPLASTIKE

Da bi ovrednotili dolgotrajne klinične učinke PTA renalnih arterij, smo pri bolnikih opravili klinični pregled in laboratorijske preiskave pred PTA in tekom (najmanj) treh mesecev po posegu. Najprimernejši bolniki za PTRA so tisti s fibromuskularno boleznijo glavne in katere od vej renalne arterije, saj je bil pri dveh tretjinah bolnikov, 5 let po posegu, učinek na krvni pritisk dober. Podobno velja tudi za bolnike z arteriosklerotično zožitvijo renalne arterije kot tudi za radiološke vidike PTA, tehnične standarde posega, komplikacije ter število ponovnih dilatacij.

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