Percutaneous transluminal angioplasty between 1998 and 2002: Outcomes of interventions proximal and distal to the inguinal ligament

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Objective: The aim of this study was to examine patients who have undergone percutaneous transluminal angioplasty (PTA) in order to describe patient characteristics and outcomes of interventions proximal and distal to the inguinal ligament and to assess whether different living situations may be associated with the outcome of PTA-intervention.

Design: A retrospective descriptive chart review.

Setting: A Swedish University Hospital between January 1998 and December 2002.

Participants: All patients who have undergone PTA.

Main outcome measure: Medical and nursing records from medical, surgical, orthopedic, and geriatric clinics were reviewed to obtain data. A study-specific protocol was developed.

Results: Eighty-seven patients were treated with PTA proximal and 101 distal to the inguinal ligament. No significant differences regarding outcome were found. Fifty-two patients had hematoma/bruise as a complication, which was more common among non-diabetic patients; 46 without diabetes versus 6 diagnosed with diabetes ($p = 0.001$). When comparing patients living situations and mortality, 76 of the deceased patients had been living alone compared to 38 of the survivors ($p = 0.001$).

Conclusions: The patients were younger in the proximal group, however no differences in outcome were found between patients who had undergone PTA whether proximal or distal to the inguinal ligament. Hematomas/bruises as a complication were more common among non-diabetic patients. Amputation was a strong predictor of death during follow-up.

Keywords: angioplasty, balloon, peripheral vascular diseases, treatment outcome

Introduction

Peripheral arterial disease (PAD) is usually due to arteriosclerosis. It can be asymptomatic or manifest as critical limb ischemia or intermittent claudication (Way 1994; Sabiston and Lyerly 1997). PAD also indicates a more general arteriosclerosis, which may lead to cardiac infarction or stroke. These patients are more likely to die from cardiovascular disease compared to healthy people of the same age (Norgren et al 2007). It is well known that PAD increases with age. The prevalence of PAD in an American community is 3% in the age range 40–59 years, 8% at 60–69 years, and 19% ≥70 years (Pasternak et al 2004). In a Swedish study the overall prevalence of PAD was 4.1% in the age range 50–89 years, which translates into approximately 2,000/100,000 in the total population (Skau and Jonsson 1993). Risk factors for arteriosclerosis apart from age are tobacco smoking (Willigendael et al 2004; Aronow 2007), diabetes, hypertension, and hyperlipidemia (Aronow 2007). Today it seems PAD is equally prevalent among men and women (Higgins and Higgins 2003; Selvin and Erlinger 2004; Collins et al 2006), although women have a higher prevalence than men of asymptomatic PAD diagnosed with ankle-brachial index according to Sigvant and colleagues (2007).

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Percutaneous transluminal angioplasty (PTA) as an intervention is less invasive and is associated with lower mortality and less risk of major morbidity than bypass surgery. Compared to bypass surgery, PTA shortens the time needed to the return to normal activities (Norgren et al 2007). PTA is also less expensive than by-pass surgery (Adam et al 2005) and can be used as a first course of treatment or as a complement to other types of surgery. Short-term outcomes at 6 months show a limb salvage rate of 97% (Mousa et al 2005) and in a one-year follow-up study none of the 78 patients required amputation (Krankenberg et al 2005). Long-term follow up at 7 years shows a limb salvage rate of 93% (Kudo et al 2005). There are no differences in duration of patency between men and women regarding outcomes after PTA (Abando et al 2005). A major significant risk factor for adverse outcome after PTA-intervention is smoking history (Kudo et al 2005). There is, however, little known concerning how different living situations are associated with the outcome of PTA-intervention.

The aim of this study is to describe the characteristics of all patients who have undergone PTA at a University Hospital in Sweden between 1998 and 2002 and to describe the outcomes of interventions proximal and distal to the inguinal ligament. Further, to explore whether different living situations may be associated with outcomes after PTA intervention.

Method

Study design

A study-specific protocol was developed on the basis of scientific literature in the area and clinical expertise, ie, two specialist surgeons and one specialist nurse experienced in the handling of vascular patients. The protocol included: age, gender, legal and social status, home help service, anatomic treatment location, smoking history, diseases (eg, diabetes, myocardial infarction, stroke, and hypertension), ulcers, pain before and after the intervention, and complications after the endovascular treatment such as hematoma at the puncture site, repeated revascularizations and re-operations of the same vessel, amputation of the limb, and survival rate. The intention was to capture both nursing and medical variables. The protocol was first tested for relevance in ten case records. A few variables were then added to the final version: other diseases (rheumatoid arthritis and renal dysfunction) and the postoperative appraisal of the radiologists. The data collection was made by one person (LE) and the extracted data was verbatim from the patient records. Where there were uncertainties, these were discussed with the vascular surgeons until consensus was reached. Prior to the data analysis, individual National Registration Records were checked to assess which patients were deceased.

Data collection and analyses

All patients treated with PTA due to PAD at a University Hospital in Sweden between January 1st, 1998 and December 31st, 2002 were included in the present study. Only the first endovascular (PTA) intervention during the period per patient was included. Any vascular/endovascular operations prior to the study period are termed "previous operations" and procedures after the PTA-intervention on the same leg are referred to as "re-PTA/re-operations". The catchment area of the hospital covered a mainly urban population of 450,000 people. The follow-up time period differed for the assessment of amputation and that of determining living status. The follow-up period for assessing amputation was between 2003 and 2005 in parallel with the data extraction from the patients' medical records. Individual National Registration Records were assessed to identify those who were deceased following completion of the medical record review, ie, in January 10th, 2006.

The variables were converted into numerical data and analyzed using the Statistical Package for Social Sciences, version 14.0 (SPSS inc., Chicago, IL, USA). As none of the variables, with the exception of age, fulfilled the assumption of normal distribution, nonparametric methods were used. The Pearson Chi-square test was used to test the differences between two independent groups of nominal-level data. For age, the Student's t-test was used. P-values ≤ 0.01 were considered as statistically significant as correction for mass-significance.

Data sources

Swedvasc, the nationwide registry of vascular and endovascular surgery in Sweden, was used by permission from its Board to identify the sample and for data collection; eg, anatomic treatment location, revascularizations and re-operations. Medical and nursing records of all patients from medical, surgical, orthopedic and geriatric clinics at the University Hospital were reviewed to obtain additional data.

Ethical considerations

The Karolinska Institutet Ethics Committee North approved the study.

Results

Demographic data and medical status/history

A total of 188 patients were included in the study, 77 (41%) men and 111 (59%) women. The mean age of the patients was

71 ± 10.1 years, range 40–90 years. Women were older with a mean age of 73 ± 10 years, men 69 ± 9.9 years ($p < 0.01$). Ninety-nine patients (55%) were married or cohabitants. More women, 61 (58%), lived alone than men, 20 (26%) ($p < 0.001$). The majority of the patients 149 (83%) were smokers or former smokers. Regarding smoking habits, 69 (93%) of the men and 80 (75%) of the women were smokers or former smokers ($p = 0.002$). Fifty-five patients (29%) were diagnosed with diabetes, 74 (39%) with heart disease, and 37 patients (20%) had undergone previous vascular operations. No differences were found regarding gender in relation to diabetes, heart disease, or previous vascular operations (Table 1).

Reason for admission, ischemia, or claudication

Seventy patients (40%) had symptoms classified as critical ischemia and 105 (60%) had symptoms classified as intermittent claudication by the vascular surgeon. For 13 cases, ischemia or claudication as reason for admission was not found in the files. Twenty out of 70 patients (29%) with ischemia were later amputated (mean follow-up was 62 months, median 65; range 25–89 months) compared to 4 out of 105 (4%) in the claudication group ($p < 0.001$). No differences were found regarding reason for admission in relation to gender, age, living situation, smoking history, diabetes, heart diseases, previous vascular operations, anatomic treatment location, the radiologists' postoperative appraisals, complications, re-PTA, re-operation or death (Table 2).

Anatomic treatment location

Eighty-seven patients (46%) were treated with PTA proximal and 101 (54%) distal to the inguinal ligament. The patients were younger in the proximal group where 59 out of 87 patients (68%) were between 40–74 years compared to 46 out of 101 (46%) in the distal group ($p = 0.002$). Eighty patients out of 87 (92%) in the proximal group were smokers or former smokers compared to 69 out of 101 (68%) in the distal group ($p < 0.001$). No differences were found regarding anatomic treatment location in relation to gender, living situation, diabetes, heart disease, previous vascular operations and reason for admission or outcomes such as complications, re-PTA, re-operations, amputation or death (Table 3).

Table 1 Demographic data and medical status/history in patients treated with percutaneous transluminal angioplasty

	Total		**Men**		**Women**		**p-value**
	n = 188		**n = 77**	**(41%)**	**n = 111**	**(59%)**	
Age, mean (range)	71	(40–90)	69	(40–90)	73	(45–90)	<0.001
Standard deviation	10.1		9.9		10		
Living situation							
Cohabitant[a]	99	55%	54	74%	45	42%	
Living alone	81	45%	20	26%	61	58%	<0.001
No information	8		3		5		
Smoking							
Smokers or former smokers	149	83%	69	93%	80	75%	
Nonsmokers	31	17%	5	7%	26	25%	0.002
No information	8		3		5		
Diabetes							
Yes	55	29%	25	33%	30	27%	
No	133	71%	52	67%	81	73%	0.42
Heart disease							
Yes	74	39%	31	40%	43	39%	
No	114	61%	46	60%	68	61%	0.834
Previous vascular operation							
Yes	37	20%	17	22%	20	18%	
No	151	80%	60	78%	91	82%	0.491

Notes: [a]Living together with partners, spouses or children (n = 3); Chi-square analysis used for all data except for age, where students t-test was used.

Table 2 Reason for admission: ischemia, or claudication

	Total		Ischemia	Claudication	p-value
	n = 175		n = 70	n = 105	
Gender					
Male	73	42%	28	45	
Female	102	58%	42	60	0.707
Age					
40–74 years	99	57%	39	60	
75 years and older	76	43%	31	45	0.852
Living situation					
Cohabitant	95	56%	36	59	
Living alone	74	44%	31	43	0.598
Missing	6		3	3	
Smoking					
Smokers or former smokers	140	83%	53	87	
Nonsmokers	29	17%	16	13	0.084
Missing	6		1	5	
Diabetes					
Yes	52	30%	27	25	
No	123	70%	43	80	0.036
Heart disease					
yes	68	39%	28	40	
no	107	61%	42	65	0.8
Previous vascular operation					
Yes	31	18%	13	18	
No	144	82%	57	87	0.808
Anatomic treatment location					
Proximal to inguinal ligament	83	47%	28	55	
Distal to inguinal ligament	92	53%	42	50	0.108
Radiologist postop appraisal					
Successful	156	91%	57	99	
Unsuccessful	16	9%	11	5	0.012
Missing	3		2	1	
Hematoma					
Yes	50	29%	20	30	
No	125	71%	50	75	1
Re-PTA					
Yes	26	15%	12	14	
No	149	85%	58	91	0.488
Re-operation					
Yes	35	20%	20	15	
No	140	80%	50	90	0.021

(*continued*)

Table 2 (*continued*)

	Total		Ischemia	Claudication	p-value
	n = 175		n = 70	n = 105	
Amputated					
Yes	24	14%	20	4	
No	151	86%	50	101	<0.001
Deceased					
Yes	68	39%	35	33	
No	107	61%	35	72	0.014

Note: Chi-square analysis used for all data; No reason for admission regarding ischemia or claudication for n = 13.

Table 3 Anatomic treatment location, proximal or distal to the inguinal ligament

	Total		Proximal	Distal	p-value
	n = 188		n = 87	n = 101	
Gender					
Male	77	41%	34	43	
Female	111	59%	53	58	0.627
Age					
40–74 years	105	56%	59	46	
75 years and older	83	44%	28	55	0.002
Living situation					
Cohabitant	99	55%	47	52	
Living alone	81	45%	38	43	0.94
Missing	8		2	6	
Smoking					
Smokers or former smokers	149	83%	80	69	
Nonsmokers	31	17%	4	27	<0.001
Missing	8		3	5	
Diabetes					
Yes	55	29%	22	33	
No	133	71%	65	68	0.267
Heart disease					
Yes	74	39%	34	40	
No	114	61%	53	61	0.942
Previous vascular operation					
Yes	37	20%	18	19	
No	151	80%	69	82	0.747
Reason for admission					
Ischemia	70	40%	28	42	
Claudication	105	60%	55	50	0.108
Missing	13		4	9	
Radiologist postop appraisal					
Successful	166	91%	79	87	
Unsuccessful	17	9%	5	12	0.152

(*continued*)

Table 3 (*continued*)

	Total		Proximal	Distal	p-value
	n = 188		n = 87	n = 101	
Missing	5		3	2	
Hematoma					
Yes	52	28%	26	26	
No	136	72%	61	75	0.527
Re-PTA					
Yes	27	14%	15	12	
No	161	86%	72	89	0.296
Re-operation					
Yes	38	20%	15	23	
No	150	80%	72	78	0.346
Amputated					
Yes	26	14%	11	15	
No	162	86%	76	86	0.662
Deceased					
Yes	76	40%	37	39	
No	112	60%	50	62	0.585

Note: Chi-square analysis used for all data.

Hematoma/bruise as an access site complication

Fifty-two patients (28%) had hematoma/bruise as a complication. This complication was more common among non-diabetic patients; 46 out of 133 patients (35%) without diabetes versus 6 patients out of 55 (11%) diagnosed with diabetes ($p = 0.001$). No differences were found regarding hematoma/bruise in relation to gender, age, heart disease, previous vascular operations, anatomic treatment location, re-PTA, re-operations, or amputation (Table 4).

Amputation

Twenty-six PTA-patients (14%) were amputated during the observation period. The mean follow-up time was 62 months (median 65; range 25–89 months). Eleven out of 38 patients (29%) who had undergone re-operation were amputated compared to 15 of the 150 (10%) not re-operated ($p = 0.003$). Most of the patients who had undergone amputation, 22 out of 26 (85%) died during the observation period compared to only 54 out of 162 (33%) patients not requiring amputation ($p < 0.001$). No differences were found regarding amputation rate in relation to gender, age, smoking history, previous vascular operations, anatomic treatment location, or re-PTA (Table 5).

Mortality

Seventy-six PTA-patients (40%) died during the observation period. Mean length of follow-up was 74 months (median 78; range 39–95 months). When comparing patients living situation and mortality, 43 of the 76 deceased patients (61%) were living alone, compared to 38 of the 112 survivors (35%), ($p = 0.001$). There was a difference between patients with and those without heart disease regarding mortality. Forty patients out of 74 (54%) diagnosed with heart disease died during the observation period compared to 36 of the 114 patients without heart disease diagnosis (32%), ($p = 0.002$). Twenty-four of the 76 patients who died had previously undergone vascular operations (32%) compared to 13 out of the 112 survivors (12%) ($p = 0.001$). No differences were found regarding mortality in relation to gender, age, smoking history, diabetes, reason for admission, anatomic treatment location, radiologists´ postoperative appraisal, complications, re-PTA, or re-operation (Table 6).

Discussion

In this study the characteristics of patients with PAD undergoing PTA were examined. The consequences of living with PAD can be pain and reduced walking ability as well as the prospect of future amputation and changed living situations.

Table 4 Hematoma/bruise as an access site complication after PTA intervention

	Total		Bleeding/hematoma	No bleeding/hematoma	p-value
	n = 188		n = 52	n = 136	
Gender					
Male	77	41%	20	57	
Female	111	59%	32	79	0.667
Age					
40–74 years	105	56%	32	73	
75 years and older	83	44%	20	63	0.332
Smoking					
Smokers or former smokers	149	83%	40	109	
Nonsmokers	31	17%	9	22	0.803
Missing	8		3	5	
Diabetes					
Yes	55	29%	6	49	
No	133	71%	46	87	0.001
Heart disease					
Yes	74	39%	20	54	
No	114	61%	32	82	0.876
Previous vascular operation					
Yes	37	20%	9	28	
No	151	80%	43	108	0.613
Anatomic treatment location					
Proximal to inguinal ligament	87	46%	26	61	
Distal to inguinal ligament	101	54%	26	75	0.527
Re-PTA					
Yes	27	14%	6	21	
No	161	86%	46	115	0.495
Re-operation					
Yes	38	20%	15	23	
No	150	80%	37	113	0.068
Amputated					
Yes	26	14%	6	20	
No	162	86%	46	116	0.574

Notes: Chi-square analysis used for all data.

The main object to be explored was whether there was a difference in outcomes or not between interventions proximal or distal to the inguinal ligament. We found no differences in outcomes between the two groups but the patients in the present study were younger in the proximal group than in the distal group. A higher percentage of patients in the proximal group were also smokers or former smokers. It is well known that smokers are diagnosed with PAD approximately ten years earlier than non-smokers (Norgren et al 2007) and that smokers have more proximal problems (Aboyans et al 2007). We chose to put smokers and former smokers in the same group because the prevalence of PAD among former smokers is closer to that of current smokers than the prevalence of PAD among never-smokers (Willigendael et al 2004).

Patient records were used in the data collection. Recording errors may have occurred during examinations and

Table 5 Amputation as an outcome after PTA intervention

	Total		Amputated	Not amputated	p-value
	n = 188		n = 26	n = 162	
Gender					
Male	77	41%	7	70	
Female	111	59%	19	92	0.117
Age					
40–74 years	105	56%	10	95	
75 years and older	83	44%	16	67	0.054
Smoking					
Smokers or former smokers	149	83%	21	128	
Nonsmokers	31	17%	4	27	0.862
Missing	8		1	7	
Diabetes					
Yes	55	29%	13	42	
No	133	71%	13	120	0.012
Heart disease					
Yes	74	39%	16	58	
No	114	61%	10	104	0.013
Previous vascular operation					
Yes	37	20%	4	33	
No	151	80%	22	129	0.553
Anatomic treatment location					
Proximal to inguinal ligament	87	46%	11	76	
Distal to inguinal ligament	101	54%	15	86	0.662
Re-PTA					
Yes	27	14%	4	23	
No	161	86%	22	139	0.873
Re-operation					
Yes	38	20%	11	27	
No	150	80%	15	135	0.003
Deceased					
Yes	76	40%	22	54	
No	112	60%	4	108	<0.001

Note: Chi-square analysis used for all data.

documentation by the nurses/surgeons, and later, during the collection and interpretation of data (Aaronson and Burman 1994). When inconsistency of documentation was found the source considered most reliable was used (Eder et al 2005) and entered in the protocol, for example vascular diagnoses described by vascular surgeons instead of orthopedics.

There were more women than men in this study. Women had a higher mean age and a higher percentage also lived alone compared to men. When comparing mortality of patients with different living situations, a significantly higher number of those deceased during the follow-up period had been living alone. A possible explanation for this might be age, since those living alone in the present study were more often women. One other gender difference was smoking habits. Men were more often smokers or former smokers than women. In the future this may change as more women in Sweden smoke today (WHO 2005) and as they have more narrow blood vessels from the beginning.

Hematoma/bruise as an access site complication was three times more common among non-diabetic patients

Table 6 Mortality after PTA intervention at follow up

	Total		Deceased	Survivors	p-value
	n = 188		n = 76	n = 112	
Gender					
Male	77	41%	26	51	
Female	111	59%	50	61	0.121
Age					
40–74 years	105	56%	35	70	
75 years and older	83	44%	41	42	0.026
Living situation					
Cohabitant	99	55%	28	71	
Living alone	81	45%	43	38	0.001
Missing	8		5	3	
Smoking					
Smokers or former smokers	149	83%	58	91	
Nonsmokers	31	17%	13	18	0.755
Missing	8		5	3	
Diabetes					
Yes	55	29%	25	30	
No	133	71%	51	82	0.366
Heart disease					
Yes	74	39%	40	34	
No	114	61%	36	78	0.002
Previous vascular operation					
Yes	37	20%	24	13	
No	151	80%	52	99	0.001
Reason for admission					
Ischemia	70	40%	35	35	
Claudication	105	60%	33	72	0.014
Missing	13		8	5	
Anatomic treatment location					
Proximal to inguinal ligament	87	46%	37	50	
Distal to inguinal ligament	101	54%	39	62	0.585
Radiologist postop appraisal					
Successful	166	91%	63	103	
Unsuccessful	17	9%	9	8	0.228
Missing	5		4	1	
Hematoma					
Yes	52	28%	16	36	
No	136	72%	60	76	0.095
Re-PTA					
Yes	27	14%	6	21	
No	161	86%	70	91	0.037

(*continued*)

Table 6 (*continued*)

	Total		Deceased	Survivors	p-value
	n = 188		n = 76	n = 112	
Re-operation					
Yes	38	20%	18	20	
No	150	80%	58	92	0.329
Amputated					
Yes	26	14%	22	4	
No	162	86%	54	108	<0.001

Note: Chi-square analysis used for all data.

than those with diabetes. A possible explanation for this might be that patients diagnosed with diabetes have more severe arterioscleroses in distal arteries of the lower limb, while they have less proximal arteriosclerosis compared to patients with PAD without diabetes (van der Feen et al 2002; Aboyans et al 2007). In Swedvasc only 7 of the patients were registered as having hematoma as a complication. When reviewing the medical and nursing records we discovered another 45 patients with hematoma/bruise recorded as a complication. All hematomas/bruises documented in the patients' records were included in this study. One possible explanation for the discrepancy between data sources is that there might be a difference in documentation between nurses and surgeons. The post-PTA examinations of the patients were made and documented by nurses and in this hospital, surgeons made the registrations in Swedvasc. Results from other PTA-studies, where the criteria for defining a hematoma are not provided, show a lower rate of hematoma as a complication. For example four cases of hematoma out of 66 patients (Mousa et al 2005), two minor groin hematoma out of 104 interventions (Krankenberg et al 2005), and nine out of 318 interventions had bleeding as a complication after PTA (Armstrong et al 1992) in previous studies. Further studies of how the hematoma/bruise complication affects the daily life are needed.

Amputation was a strong predictor of death during follow-up since most of the patients who had undergone amputation (85%) died during the observation period compared to patients not requiring amputation (33%). Amputation as an intervention in itself is not a strong predictor of death, but rather, the need of amputation indicates a severe underlying arteriosclerosis. The severe arteriosclerosis on the other hand is a strong predictor of death (Norgren et al 2007).

The ambition of the study was to also be able to describe the nursing care of these patients and medical outcome. Nursing variables such as pain, pain relief, ulcers, and home help service included in the protocol from start were not usable because documentation concerning these variables was rarely present in the records of the patients or in Swedvasc. It is clearly a deficiency that the quality registries do not contain nursing variables. A better general view of the overall health of the patients would be obtained if nursing variables were included.

Conclusion

This study confirms the well-known facts of increased risk for arteriosclerosis in smokers. Hematomas/bruises as a complication were more common among nondiabetic patients. The patients were younger in the proximal group, however no differences in outcome were found between patients who had undergone PTA whether proximal or distal to the inguinal ligament. Amputation was a strong predictor of death during follow-up period. A majority of the deceased patients had been living alone.

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