Standard Method of Assessing Relative Effectiveness of Therapies for Arterial Occlusive Diseases *

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RESULTS of thromboendarterectomy and of arterial homografts in the treatment of arterial occlusive disease have been compared[3] by the *life table* method of reporting data. This method shows the frequency of failure at specific intervals and provides a basis for accurately comparing failure rates of different groups of patients. The life table method emphasizes differences in rates of failure at different times after operation. This study was undertaken to: 1) establish a simple method of classification of the extent of arterial occlusive disease in order to permit a valid comparison to be made of failure rates among different groups of patients; 2) describe long-term results of homografts and early failure rates of synthetic arterial substitutes in the treatment of patients with arterial occlusive disease; and 3) define the prognostic value of arteriographic patency of the arterial system beyond major arterial occlusions. Effects of therapy upon mortality, viability of the extremities, and duration of arterial patency also are presented.

Life Table Analysis

The life table method (Table 1, 2) identifies those patients or extremities at risk for each postoperative time interval after operation. The term *at risk* defines those patients followed at least for the designated months (Table 1, col. 1) but does not include patients whose postoperative course (follow up) is less than the interval (col. 6). The number of patients at risk in any interval represents total patients population less cumulative failures (col. 4) and those patients (col. 6) whose postoperative course is less than the time indicated. The latter group thus affects neither failure or success rate in the succeeding groups. Accumulative failures for the series is the sum of column 4, Tables 1 and 2. Tables 1 and 2 show the failure incidence at three-month intervals for aortic-iliac and femoropopliteal occlusive disease after operations. It is apparent that the rates of failure were highest in the first three months after both types of operative therapy (Fig. 1, 2). The number of patients with open arteries two years after operation was greater after aortic thromboendarterectomy than after aortic arterial substitution (Table 3). Among patients with femoral arterial occlusions, however, the failure rate two years after arterial substitution did not differ significantly from the two year failure rate after thromboendarterectomy (Table 3).

Functional and Anatomic Staging of Arterial Disease

The life table method accurately describes the frequencies of failures at specific intervals but does not insure that the therapeutic groups have comparable anatomic and functional arterial occlusive disease. Obviously such comparability is a necessary prerequisite to the valid assessment of therapeutic results. A method of classification identifying the site of occlu-

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TABLE 1. *Life Table Failure Rates after Operations for Aortic-Iliac Arterial Occlusive Disease*

Months at Risk		No. Patients at Risk	Failed During Interval	Interval Failure Rate %	Patients' Follow Up Terminated in Interval***
<1	TEA*	79	10**	13	0
	Graft	36	6****	17	0
1– 4	TEA	69	2	3	1
	Graft	30	1	3	3
4– 7	TEA	66	0	0	10
	Graft	26	1	4	0
7–13	TEA	56	0	0	11
	Graft	25	3	12	2
13–19	TEA	45	1	2	10
	Graft	20	1	5	2
19–25	TEA	34	0	0	5
	Graft	17	1	6	0
25–37	TEA	29	1	3	8
	Graft	16	1	6	0
37–49	TEA	16	0	0	9
	Graft	15	1	7	4
49–60	TEA	7	0	0	0
	Graft	10	0	0	2

* Thromboendarterectomy.

** 6 patients died postoperatively (8%), 3 occluded one side of the endarterectomy postoperatively, and 1 had external iliac artery ligation incident to technical error.

*** These patients not considered *at risk* in successive intervals.

**** 5 patients died postoperatively (14%).

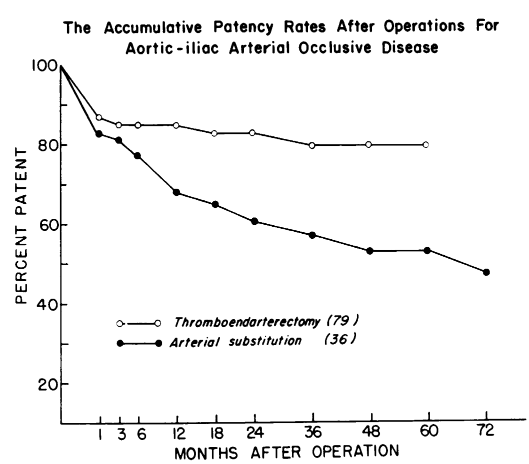

FIGURE 1.

sion and clinical stage of the occlusive disease is of aid in establishing this prerequisite.

Stages of Arterial Occlusive Disease

Anatomical Group:

I. Aortic-iliac occlusive disease predominating (absent or diminution in femoral pulses; angiographic evidence of open femoropopliteal arteries).

II. Femoropopliteal occlusions predominating (femoral pulses present; distal pulses absent).

III. Combined aortic-iliac and femoropopliteal disease.

Functional Group:

A. With exercise claudication only

B. Advanced disease; exercise claudication plus any of the following:
1. Ischemic pain at rest, requiring medication for relief
2. Ulceration of skin of the extremity
3. Gangrene
4. Diabetes mellitus (only seven persons in this series had diabetes mellitus)

This classification allows identification of the site of major occlusion and of significant clinical factors which apparently relate to the course of the disease. Thus, all patients of Group B are identified as having advanced occlusive disease whatever the anatomic locations of major occlusions. The presence of claudication plus any of the criteria listed is associated usually with unfavorable prognosis regardless of therapy. The proportion of Group B patients included in a reported series might be expected to affect results significantly (i.e. amputation incidence is higher in diabetics than non-diabetics with similar symptoms and signs).

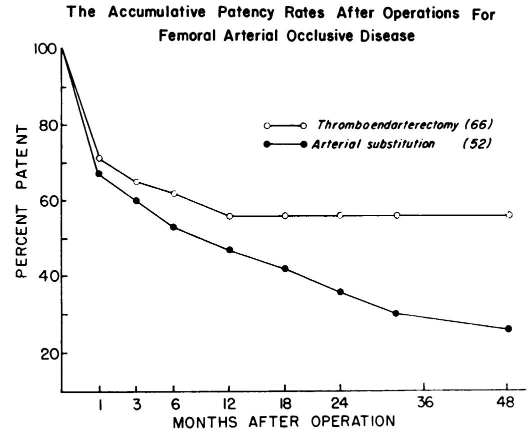

FIGURE 2.

Advanced ischemia (Group B) was

TABLE 2. *Life Table Failure Rates after Operations for Femoral Arterial Occlusive Disease*

Months at Risk		No. Patients at Risk	Failed During Interval	Interval Failure Rate %	Patients' Follow Up Terminated in Interval***
<1	TEA*	66	19**	29	1
	Graft	52	17	33	0
1- 4	TEA	46	4	9	1
	Graft	35	4	11	3
4- 7	TEA	41	2	5	5
	Graft	28	3	11	1
7-13	TEA	34	3	9	9
	Graft	24	3	13	1
13-19	TEA	22	0	0	9
	Graft	20	2	10	3
19-25	TEA	13	0	0	4
	Graft	15	2	13	2
25-37	TEA	9	0	0	5
	Graft	11	2	18	2
37-49	TEA	4	0	0	4
	Graft	7	1	14	3

* Thromboendarterectomy.
** Two patients lost to follow up.
*** These patients not considered *at risk* in successive intervals.

TABLE 3. *Two-Year Results of Thromboendarterectomy and Arterial Substitution in the Treatment of Aortic-Iliac and Femoropopliteal Occlusive Disease*

	No. Patients Operated Upon 2 or More Years Ago	No. Living Patients with Patent Operative Sites 2 Years After Operation	No. Patients Dying or Developing Operative Site Occlusion in 2 Postoperative Years
Aortic-iliac Occlusions			
a) Arterial substitution	30	16	14
b) Thromboendarterectomy	44	34	10
Totals	74	50	24
Comparing a with b,	Chi Square = 4.7	P = .04	
Femoropopliteal Occlusions			
a) Arterial substitution	34	11	23
b) Thromboendarterectomy	35	17*	16
Totals	69	28	39

* Three patients died with open arteries 10, 13 and 17 months after operation.
Failure rates two years after operation in the two series did not differ (Chi Square = 1.2, P = 0.27).

known to exist in 65 of 111 patients having operations for femoropopliteal disease (58%). Nineteen patients operated upon for femoral arterial occlusive disease required subsequent amputation; 16 were functionally Group B and *only* 3 Group A. Variations in the size of this unfavorable group within a series undoubtedly explains much of the differences in reported results

AMPUTATION INCIDENCE AND STAGE OF FEMORAL ARTERIAL DISEASE

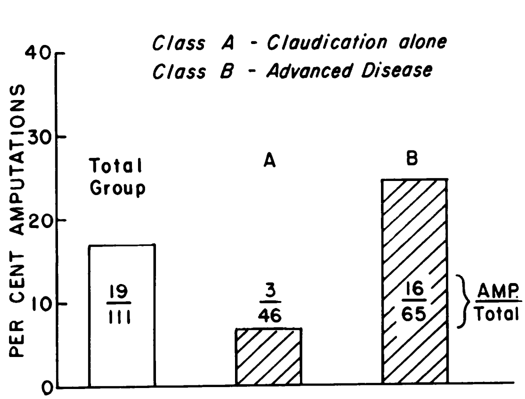

FIGURE 3.

for nonoperative and surgical therapy (Fig. 3). Less than 5.0 per cent of non-diabetic patients with claudication *only* (Group A) lose extremities so that results as determined by amputation requirements of any therapeutic regimen are satisfactory.[1, 2] When advanced ischemia exists, however, the alternatives are usually: 1) attempted revascularization; or 2) amputation. Nonoperative theory uniformly fails. In patients with advanced arterial disease (Group B), operative therapy is the only method at present available which may salvage the extremities. The majority of patients (58.4%) with femoropopliteal occlusive disease in this series had operative therapy because of imminent gangrene or intractable pain with amputation as the only alternative. Twenty-six (57.8%) of these extremities were preserved.

Table 4 shows the incidence of advanced ischemic factors and relates the classification and staging to end results in this group of patients. There was no difference in the frequency of advanced ischemic factors in

TABLE 4. *Occlusive Disease Stage Related to Early Failure Rates*

	Femoropopliteal Arteries Class			
	II-A Claudication Alone		II-B Advanced Ischemia	
Therapy	Total	Failed	Total	Failed
Homografts	19	10	8	7
Synthetic grafts	6	2	12	7
Thromboendarterectomy	26	11	33	21
Totals	51	23(45%)	53	35(66%)

the two therapeutic groups. One year failure rate in femoropopliteal occlusions for Class II-A was 42% compared to 64% for Class II-B (advanced ischemia). Though staging can be refined by arteriographic criteria it does provide a basis for comparing different therapies in reasonably similar patient groups.

Prognostic Value of Arteriography

Arteriography was used to determine the site of disease and the status of the arteries distal to the major arterial obstruction. Narrowing of arteries distal to the site of revascularization influences the frequency of postoperative occlusion apparently limiting the rate of blood flow from the operative site. Preoperative arteriograms of 190 patients in this series were reviewed and classified without knowledge of the postoperative results in an effort to assess the severity of arterial disease distal to the major occlusion (Table 5). A numerical value relating to the number of arterial branches seen beyond the major obstruction was assigned each case in order to weight the severity of disease beyond femoral arterial occlusions. Weighted severity values were nearly the same in the two therapeutic groups (Table 6). Lack of patency of the popliteal artery beyond the principal site of femoral arterial occlusion was associated with a high rate of failure. Advanced occlusive disease of the popliteal

TABLE 5. *A Classification of Arterial Occlusions Beyond the Operative Site Based Upon Preoperative Arteriography*

Operative Site

1. Aortic-iliac arteries
   a) Outflow tract impaired if occlusion present in the right or left femoral or deep femoral arteries.
   b) Outflow treact unimparied when occlusion not demonstrated in the femoral or deep femoral arteries.
2. Femoropopliteal arteries

	Branches Visualized	Weighted Factor
a) Popliteal artery patent:	0	3
	1	2
	2	1
	3	0
b) Popliteal artery occluded:	0	15
	1	12
	2	9
	3	6

TABLE 6. *Arteriographic Outflow Patency Related to Failures*

	Outflow Patent	Outflow Occluded	Total*
Femoral			
TEA**	53	10	63
Grafts	44	5	49
Total	97	15	112
Early failure	22(23%)	8(53%)	
Aortic-Iliac			
TEA	40	25	65
Grafts	22	11	33
Total	62	36	98
Early failure	11(18%)	13(36%)	

* Arteriograms examined.
** Thromboendarterectomy.

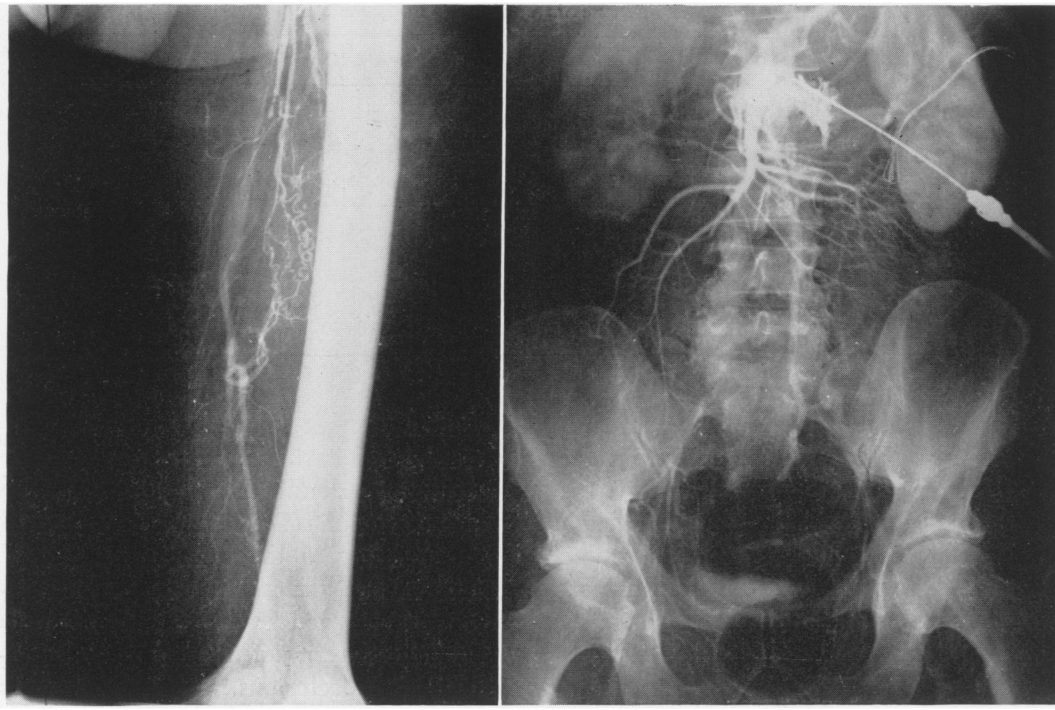

FIG. 4. Operative arteriogram demonstrates established collateral circulation about a segmental femoral artery occlusion. Aortography failed to visualize distal femoral arteries adequately because of proximal complete aortic obstruction

artery or its major branches with proximal removal of femoral artery obstruction was associated with early thrombosis in eight of 15 patients (53%); only 22 of 97 femoral arteries (24%) thrombosed postoperatively when arteriographically patent popliteal arteries existed (chi square = 6.25, P. = .013).

The incidence of subsequent thrombosis in the operative site was 36 per cent among

TABLE 7. *Incidence of Postoperative Complications*

Type of Operation	No. Patients	Deaths	No. Patients Undergoing a Major Amputation: Postoperatively	No. Patients Undergoing a Major Amputation: Later	No. Infections
Femoral-arterial					
Substitution	52	1	11	5	6
Endarterectomy	66	1	8	3	1
Totals	118	2	19	8	7
Aortic-iliac					
Substitution	36	5	0	0	2
Endarterectomy	79	6	1	1	1
Totals	115	11	1	1	3

patients operated upon for aortic-iliac occlusions when distal arterial disease existed and 18 per cent among those without demonstrable outflow tract occlusion. Frequencies of partial occlusion of the arteries beyond the aortic-iliac occlusions did not differ significantly in the two therapeutic groups.

Arteriograms also provide evidence in determining the extent of artery reconstruction necessary to effect adequate flow. In several patients with aortic-iliac disease the demonstration of large functional collaterals about a segmental femoral obstruction limited the procedure to the proximal arteries (Fig. 4). Arteriography during the operation was useful in demonstrating adequate distal vascular lumina when preoperative visualization of the outflow tract was not satisfactory.

Results

Two hundred thirty-three patients had operations in the Barnes Hospital for major arterial occlusive disease between 1953 and 1961. One hundred fifteen operations involved the aorta and iliac arteries and 118 the femoral and popliteal arteries. Arterial substitutes of arterial homograft or synthetic cloth were used to treat 52 of the 118 femoropopliteal arterial occlusions and 36 of the 115 aortic-iliac occlusions. Sixty-four arterial substitutes used were homografts and 24 were synthetic cloth tubes (Dacron, Teflon). Patients with aortic-iliac occlusive disease were significantly younger than patients suffering from femoropopliteal occlusions. Age and sex distributions of the patients in the two principal treatment groups did not differ when related to the specific anatomical sites of occlusion.

The mortality and complication experience is summarized in Table 7. Operative mortalities after arterial substitution procedures and after thromboendarterectomies did not differ significantly. Early amputation was required in one patient after operation upon the aorta and iliac arteries; 19 of 118 patients having femoropopliteal revascularization underwent subsequent amputation. Sixteen of the 19 had gangrene or ulceration preoperatively.

Eight serious infections developed postoperatively among the 88 patients treated by arterial substitution. Three infected substitutes were synthetic cloth and five were arterial homografts. All eight infected grafts were removed. Four patients subsequently required amputation and two died. Two wound infections occurred after 79 thromboendarterectomies. None of these individuals required amputation nor did any die because of dissolution of the artery and secondary hemorrhage.

Summary and Conclusions

Among 233 patients thromboendarterectomy for aortic-iliac disease was associated with a significantly higher success rate than arterial substitution. However, patency rates for femoropopliteal occlusions were only 10 per cent higher for thromboendarterectomy than arterial substitutes, not a significant difference.

The life table method of reporting results of revascularization showed that the largest number of failures occur in the immediate postoperative period and in the first six months after operation. *Rates* of failure for arterial substitutions and thromboendarterectomy in the extremities *at risk* were much higher during the first six postoperative months, whatever the cause, than subsequently (Table 1, 2). Failures occurring from six to 60 months probably are more attributable to either inadequacy in the therapeutic method of arterial reconstruction or to progression of the arterial disease than to technical errors and postoperative complications. The site and the stage of disease appear to affect results more decisively than does the type of operative therapy.

The prognostic significance of signs and symptoms of advanced ischemia in patients with occlusive disease of the femoral and popliteal arteries is obvious (Table 4). Almost all early amputations after attempted revascularization occurred in patients with severe rest pain, ulcer or gangrene. Unless the frequencies of advanced ischemia in different therapeutic groups are known, the efficacies of the different therapies cannot be assessed accurately.

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