Smoking and the patency of lower extremity bypass grafts: A meta-analysis

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Objective: **Smoking is the major risk factor associated with the development and progression of peripheral arterial disease (PAD). To establish the best estimate of the effect of smoking, smoking cessation, and the dose-response relationship on the patency of lower extremity bypass grafts, we performed a systematic review.**
Methods: **A search of medical articles and reviews relating to the influence of smoking on the patency of arterial reconstructive grafts in patients with PAD was made. Studies considered for inclusion were those that evaluated the influence of smoking on the primary, secondary, or cumulative patency rates of arterial reconstructive surgery in the lower extremities in patients with PAD. Primary data were used to calculate summary estimates with standard meta-analysis techniques.**
Results: **The 29 eligible studies included 4 randomized clinical trials, 12 prospective studies, and 13 retrospective studies. The effect of smoking on graft patency in the randomized clinical trials and other prospective studies had a 3.09-fold (2.34 to 4.08; $P < .00001$) increase in graft failure. A comparison of patency rates among all studies that used autogenous or polyester grafts showed no difference. A clear dose-response relationship was present, with a decreased patency in heavy smokers compared with moderate smokers. Smoking cessation restores patency rates toward the never smokers group.**
Conclusion: **Continued smoking after lower limb bypass surgery results in a threefold increased risk of graft failure. Smoking cessation, even if instigated after the operation, restored graft patency towards the patency of never smokers. These results indicate that adequate smoking cessation strategies in patients eligible for lower limb bypass surgery are of utmost importance. (J Vasc Surg 2005;42:67-74.)**

Smoking is the major risk factor associated with the development and progression of peripheral arterial disease (PAD).[1,2] Nearly all patients who require bypass surgery have accumulated a considerable number of pack-years of smoking. Often, patients with PAD appear to be less successful in smoking cessation compared with patients after a myocardial infarction.[3,4]

Numerous studies have been published on the influence of smoking on the results of graft patency in peripheral vascular reconstructive surgery.[2] Most of these studies show a negative effect of smoking on graft patency, but the differences in effect-size are substantial. The necessity to adequately summarize the available data to define an appropriate evidence-based approach with respect to the influence of smoking and smoking cessation on graft patency has long been recognised.[5]

To establish the best estimate of the effect of smoking on the patency of lower extremity bypass grafts, we performed a systematic review. We also explored a possible dose-response relationship and the effect of smoking cessation in our meta-analysis.

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METHODS

The literature search, selection of studies, the inclusion and exclusion of studies, the data extraction, and data analysis were performed by two authors independently (EW, MP).

Search strategy. A search of medical articles and reviews relating to the influence of smoking on the patency of arterial reconstructive grafts in patients with PAD from 1950 to 2004 was made in Medline, SUMsearch, the Cochrane Library, and PubMed. Search terms (MESH and free text) included peripheral arterial disease, peripheral vascular disease, claudication, smoking, nicotine, tobacco, patency, graft, bypass, stenosis, occlusion, arterial reconstruction, lower extremities, vascular surgery, arterial surgery and angioplasty. A manual search of reference lists for relevant articles was also conducted.

Selection criteria. Studies considered for inclusion were those that evaluated the influence of smoking on the primary, secondary, or cumulative patency rates of arterial reconstructive surgery in the lower extremities in patients with PAD. Graft patency was analyzed with pulse examination, Doppler studies, and arteriography, if necessary. No selection was made between graft materials. Studies were excluded when graft patency rates in smokers had not been adequately separated from nonsmokers. Also studies that

Table I. Characteristics of included studies

Study	*Pat.*	*Sex*	*Follow- up*	*Graft material*	*Graft location*	*Smoking intensity*	*Smoking assessment*
Randomized controlled trials							
Abbott[7]	244		3 yr	PTFE, D	Fem-pop, AK	No, C	Q
Burger[13]	136	77M, 59F	2 yr	ASV, PTFE	Fem-pop, AK	No, C	Q
Green[20]	240		5 yr	PTFE, D	Fem-pop, AK	N, Fo, C:1 p/d, >1 p/d	Q
Powell[45]	250		1 yr	ASV, P	Fem-pop, AK	No, C	Q
Prospective studies							
Ameli[8]	105		9 m	NR	A-fem	No, C	Q
Cheshire[14]	46		1 yr	ASV, PTFE	Infrainguinal	No, C	COHb
Giswold[16]	55	46M, 9F	13 m	RVG	Fem-pop-tib-ped	No, C	Q
Greenhalgh[23]	64		3-5 yr	ASV	A-iliac, Fem-pop	No, C	COHb
Herring[25]	161			D	Ax-fem, Ax-fem-fem	No, C	Q
Lam[30]	229			P, ASV	Infrainguinal	No, C	Q
Provan[48]	326	215M, 111F	5 yr	ASV, PTFE	Fem-pop	N, Fo, C	Q
Robicsek[51]	187		6 m-10 yr	D	A-iliac, A-fem	N, Fo, C:1 p/d, >1 p/d	Q
Rutherford[54]	249		3 yr	RVG, PTFE, ASV, UV	Infrainguinal	No, C	Q
Wiseman[61]	93	64M, 29F	2 yr	P	Fem-pop	No, C	COHb, T
Wiseman[62]	157		1 yr	ASV	Fem-pop	No, C	COHb, T
Wray[63]	50		3-6 yr	D	A-fem	No, C: cig/d	Q
Retrospective studies							
Ameli[9]	121		5 yr	ASV, PTFE, UV	Fem-pop, Fem-tib	No, C: 1-5, 6-15, 16-25, >25 cig/d	Q
Ameli[10]	73		5 yr	ASV, PTFE, UV, D	Fem-pop	No, C: 1-5, 6-15, 16-25, >25 cig/d	Q
Gentile[15]	93	55M, 38F	21m	ASV, RVG	Fem-pop, Fem-tib-ped	No, C	Q
Hall[24]	195	169M, 26F	3 yr	ASV	NR	No, C	Q
King[28]	290	141M, 41F	3 yr	RVG	Ax-fem, Ax-fem-fem	No, C: 1-15, >15 cig/d	Q
Miyazaki[39]	496		30.8 m	PTFE, D	Fem-pop, AK	No, C	Q
Myers[40]	217		6 m-5 yr	D, ASV	A-fem, Fem-pop, Fem-tib	No, C: 1- 5, 6-15, 16-25, >25 cig/d	Q
Nevelsteen[42]	792		10 yr	D	A-fem, A-bifem	No, C	Q
Powell[46]	250		1 yr	ASV, D	Fem-pop	N, Fo, C	COHb, T
Prendiville[47]	114	76M, 38F	3 yr	PTFE	AK	No, C	Q
Ramsburgh[49]	123	100M, 23F	2 yr	RVG, BV, P	Fem-pop, BK	No, C	Q
Saad[55]	40		50 m	P	Fem-pop	No, C	Q
Sayers[56]	90			PTFE	Infrainguinal, AK	N, Fo, C	Q

M, Male; *F*, female; *cig/d*, cigarettes per day; *p/d*, packs of cigarettes per day; *N*, never smoker; *No*, never and former smokers; *Fo*, former smokers; *C*, current smokers; *Q*, questioned; *T*, thiocyanate; *COHb*, carboxyhemoglobin; *ASV*, autogenous saphenus vein; *PTFE*, polytetrafluoroethylene; *UV*, umbilical vein; *RVG*, reversed; vein graft; *P*, polyester; *BV*, bovine vein; *AK*, above knee; *BK*, below knee; *A*, aorta; *NS*, not significant; *NR*, not reported.

evaluated only reoperations, critical ischemia, angioplasty, or endarterectomies were excluded.

Data extraction. Data from the included studies were extracted using a standardized form and summarized in tabular format. Each eligible study was assessed for design (prospective vs retrospective). The extracted data for smokers and nonsmokers included number, sex, and duration of follow-up of patients; graft patency, material, and location; smoking substance, intensity, and assessment of smoking status (questionnaire vs biochemical markers).

Data analysis. Where possible, outcome data—expressed in terms of patency or relative risk—were used with never smokers as the reference group. If this was not available, the nonsmokers group (never and former smokers together) was used. Different patency outcomes in the various graft materials were taken into account in the analysis. Primary data were used to calculate summary estimates with standard meta-analysis techniques. The heterogeneity between studies was assessed with a χ^2 test, using Rev-manager 4.2 supplied by the Cochrane collabo-

Table II. Overall graft patency in nonsmokers versus smokers

Study	*Number nonsmokers*	*Patency nonsmokers n (%)*	*Number smokers*	*Patency smokers n (%)*	P	*Patency*
Randomized clinical trials						
Powell[45]	19	16 (84%)	231	150 (65%)	<.02	Primary
Prospective studies						
Ameli[8]	50	44 (88%)	55	34 (62%)	<.001	Primary
Cheshire[14]	29	23 (79%)	17	7 (39%)	.016	Primary
Giswold[16]	105	88 (84%)	68	43 (63%)	<.02	Primary
Greenhalgh[23]	39	38 (97%)	25	14 (56%)	<.001	Primary
Herring[25]	10	5 (50%)	24	8 (33%)	NR	Primary
Provan[48]	20	14 (70%)	57	19 (33%)	<.001	Primary
Rutherford[54]	84	57 (68%)	162	83 (51%)	<.05	Primary
Wiseman[61]	NR	NR (78%)	NR	NR (57%)	<.05	Primary
Wiseman[62]	86	72 (84%)	71	45 (63%)	.02	Primary
Wray[63]	16	16 (100%)	30	21 (70%)	.05	Secondary
Subtotal	458	373	740	424		
Common effect	Peto OR, 3.09 (95% CI, 2.34-4.08; $P < .00001$)					
	OR, 3.23 (95% CI, 2.39-4.35; $P < .00001$)					
Retrospective studies						
Amel[9]	50	44 (88%)	55	34 (62%)	0.045	Primary
Ameli[10]	76	43 (56%)	60	29 (49%)	NS	Primary
Hall[24]	37	30 (81%)	172	119 (69%)	<0.05	Primary
Nevelsteen[42]	453	249 (55%)	339	125 (37%)	<0.05	Primary
Powell[46]	NR	NR (89%)	NR	NR (67%)	0.05	Primary
Powell[46]	NR	NR (84%)	NR	NR (63%)	0.02	Primary
Prendiville[47]	33	22 (66%)	81	32 (40%)	<0.05	Primary
Ramsburgh[49]	46	29 (62%)	102	63 (62%)	NS	Primary
Sayers[55]	10	7 (75%)	80	32 (40%)	<0.001	Secondary
Subtotal	705	424	889	434		
Common effect	Peto OR: 1.99 (95% CI, 1.62-2.47; $P < .00001$)					
	OR: 2.02 (95% CI, 1.62-2.52; $P < .00001$)					
Overall common effect	Peto OR: 2.35 (95% CI, 1.98-2.78; $P < .00001$)					
	OR: 2.39 (95% CI, 2.00-2.85; $P < .00001$)					
Total overall	1,163	797	1,629	858		

NR, Not reported; *NS,* not significant; *OR*, odds ratio.

ration. This meta-analysis was performed without external or commercial sponsors.

RESULTS

The literature search resulted in the identification of 58 potentially eligible articles.[6-63] Of these 29 had to be excluded.[6,11,12,17-19,21,22,26,27,29,31-38,41,43,44,50,52,53,57-60] Reasons for this were the absence of separate data on smokers and nonsmokers (n = 16), only on critical ischemia (n = 1), only on reoperations after graft failure (n = 3), or the data on angioplasty and grafts had not been separated (n = 3). Three articles, written in Polish, Serb, and Russian, were not included because they could not be retrieved. Two articles, describing the same study population were analyzed, and only those with the most extensive data on the influence of smoking have been included.[27,28] Two articles provided identical information and only one was included.[22,23] One review article was identified that described two reports on the subject and therefore only the cited articles have been included in the analysis.[58] No meta-analyses or systematic reviews were identified.

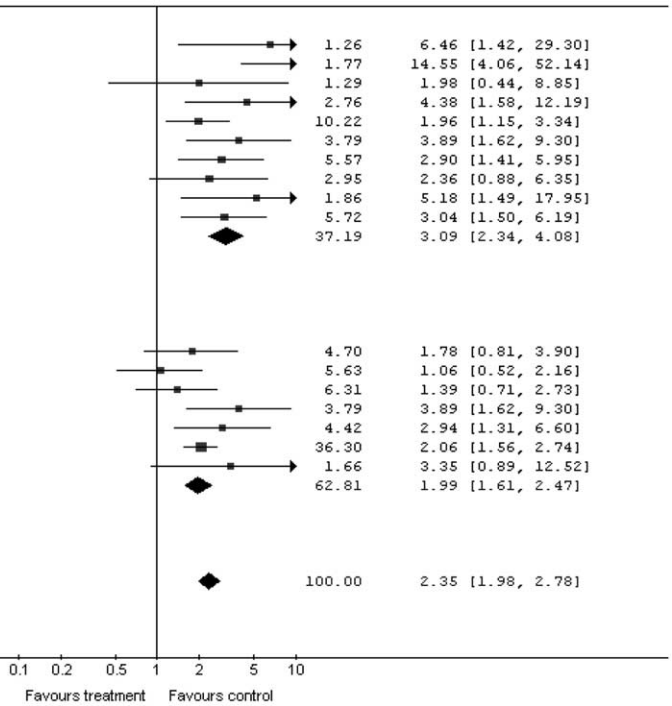
The 29 eligible studies included 4 randomized clinical trials that randomized patients to different types of grafts, 12 prospective studies, and 13 retrospective studies. The randomized clinical trials are treated in the meta-analysis as prospective studies. Details of the included studies are summarized in Table I.

Graft patency in smokers versus nonsmokers. Eleven prospective and nine retrospective studies provided data on the influence of smoking on the general patency of grafts (Table II). All but two retrospective studies showed a significant decrease in graft patency in smoking patients. Studies providing primary data on the number of smokers and nonsmokers on graft patency have been included in the meta-analysis. One prospective and one retrospective study did not provide the number of patients and were excluded from the summary estimates.[46,61]

The effect of smoking on graft patency in the prospective studies had a 3.09-fold (95% confidence interval [CI], 2.34 to 4.08; $P < .00001$) increase in graft failure (Table III). The retrospective studies showed a 1.99-fold (95% CI, 1.61 to 2.47; $P < .00001$) increase in graft failure (Table III). The overall effect of smoking on graft patency, taking prospective and retrospective studies into account, showed a 2.35-fold (95% CI, 1.98 to 2.78) increase in risk of graft failure (Table III). The analyzed studies showed no correlation between study size and patency outcome (no statistical heterogeneity detected).

Table III. The influence of smoking on graft patency in prospective and retrospective studies

Study or sub-category	Smokers n/N	Non-smokers n/N	Peto OR 95% CI	Weight %	Peto OR 95% CI
01 Prospective patency studies					
Wray	9/30	0/16		1.26	6.46 [1.42, 29.30]
Greenhalgh RM, 1	11/25	1/39		1.77	14.55 [4.06, 52.14]
Herring	16/24	5/10		1.29	1.98 [0.44, 8.85]
Provan	38/57	6/20		2.76	4.38 [1.58, 12.19]
Rutherford	79/162	27/84		10.22	1.96 [1.15, 3.34]
Ameli FM, Stein2	21/55	6/50		3.79	3.89 [1.62, 9.30]
Wiseman S, Kenc1	26/71	14/86		5.57	2.90 [1.41, 5.95]
Powell	81/231	3/19		2.95	2.36 [0.88, 6.35]
Cheshire	10/17	6/29		1.86	5.18 [1.49, 17.95]
Giswold	25/68	17/105		5.72	3.04 [1.50, 6.19]
Subtotal (95% CI)	740	458		37.19	3.09 [2.34, 4.08]
Total events: 316 (Smokers), 85 (Non-smokers)					
Test for heterogeneity: Chi² = 11.39, df = 9 (P = 0.25), I² = 21.0%					
Test for overall effect: Z = 7.95 (P < 0.00001)					
02 Retrospective patency studies					
Hall	53/172	7/37		4.70	1.78 [0.81, 3.90]
Ramsburgh	39/102	17/46		5.63	1.06 [0.52, 2.16]
Ameli FM, Stein1	31/60	33/76		6.31	1.39 [0.71, 2.73]
Ameli	21/55	6/50		3.79	3.89 [1.62, 9.30]
Prendiville	49/81	11/33		4.42	2.94 [1.31, 6.60]
Nevelsteen	214/339	204/453		36.30	2.06 [1.56, 2.74]
Sayers	48/80	3/10		1.66	3.35 [0.89, 12.52]
Subtotal (95% CI)	889	705		62.81	1.99 [1.61, 2.47]
Total events: 455 (Smokers), 281 (Non-smokers)					
Test for heterogeneity: Chi² = 8.01, df = 6 (P = 0.24), I² = 25.1%					
Test for overall effect: Z = 6.31 (P < 0.00001)					
Total (95% CI)	1629	1163		100.00	2.35 [1.98, 2.78]
Total events: 771 (Smokers), 366 (Non-smokers)					
Test for heterogeneity: Chi² = 25.41, df = 16 (P = 0.06), I² = 37.0%					
Test for overall effect: Z = 9.85 (P < 0.00001)					



OR, Odds ratio; *CI,* confidence interval.

Studies that used biochemical smoking markers to determine the smoking status of the included patients, found more outspoken differences between patency rates (3.81; 95% CI, 2.34 to 6.21), than studies that had interviewed the patients about their smoking habits (2.19; 95% CI, 1.83 to 2.63).

There was no difference between studies with a follow-up period of ≤2 years (2.50; 95% CI, 1.78 to 3.49), or studies with a follow-up period of ≥2 years (2.28; 95% CI, 1.87 to 2.79).

Six studies did not provide primary data, but five reported a higher risk of graft failure in smokers, which was significant in three. The four prospective studies showed an increased relative risk of 2.5 ($P = .0017$), 1.28 (95% CI, 0.64 to 2.55), 4.72 (95% CI 2.5 to 8.85; $P < .001$), and 1.72 (95% CI, 0.93 to 3.18; $P = .008$).[8,13,16,30] The two retrospective studies showed an increased risk in smokers of 1.59 (95% CI, 1.01 to 2.52; $P = .046$) and 0.99.[39,55]

Early graft flow disturbances are associated with future graft failure. This was analyzed in one study that showed a significant increase in early flow disturbances in the grafts of smokers.[15]

Three prospective studies evaluated the additional effect of age combined with smoking on graft patency. All studies showed that smokers <65 years old have a higher risk of graft failure than do older smokers.[7,9,20]

The effect of smoking on the patency of different graft materials. Three prospective and two retrospective studies looked explicitly into the influence of smoking on different graft materials (Table IV).[9,25,45,46,48] All, except one small prospective study that used polyester grafts, showed a decreased patency in grafts of smoking patients. The remaining studies compared autogenous saphenus vein with prosthetic femoropopliteal grafts. The two studies that provided primary data for a graft preference analysis showed no difference in the effect of smoking on graft patency between autogenous or polyester grafts in smoking patients (0.94; 95% CI, 0.58 to 1.53).[9,45] A comparison of patency rates between all studies that used autogenous or polyester grafts showed no difference in the effect of smoking in polyester grafts (2.07; 95% CI, 1.62 to 2.65; $P < .0001$) compared with autogenous grafts (2.78; 95% CI, 1.98 to 3.92; $P < .0001$) (Tables V and VI).

Smoking dose response and smoking cessation. One prospective and two retrospective studies evaluated a possible smoking dose-response relationship on graft patency.[38,40,51] All three studies showed a clear dose-response relationship, with a decreased patency in heavy smokers compared with moderate smokers (Table VII).

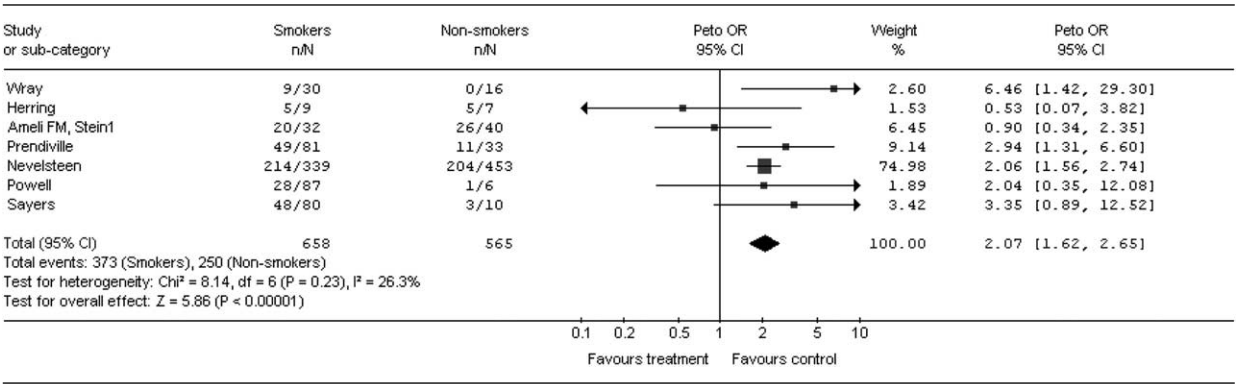
Three studies evaluated the influence of smoking cessation on graft patency.[40,48,51] Smoking cessation was instigated from the time of the bypass surgery during the hospital stay. The difference in graft patency in former smokers compared with current smokers was significantly

Table IV. Patency in different graft materials

Study	*Graft material*	*Number nonsmokers*	*Patency nonsmokers n (%)*	*Number smokers*	*Patency smokers n (%)*	P	*Patency*
Randomized Clinical Trials							
Powell[45]	ASV	13	11 (84%)	144	91 (63%)	<.02	Primary
	P	6	5 (87%)	87	59 (68%)	<.05	Primary
Prospective studies							
Herring[25]	D seeded	3	3 (100%)	15	3 (20%)	<.05	Primary
	D unseeded	7	2 (30%)	9	4 (41%)	NS	Primary
Provan[48]	ASV	20	14 (70%)	57	24 (42%)	<.001	Primary
	PTFE	NR	NR (70%)	NR	NR (16%)	<.001	Primary
Retrospective studies							
Ameli[9]	ASV	36	27 (74%)	28	17 (60%)	NR	Primary
	P	40	14 (35%)	32	12 (39%	NR	Primary
Powell[46]	ASV	NR	NR (89%)	NR	NR (67%)	.05	Primary
	P	NR	NR (84%)	NR	NR (63%)	.02	Primary

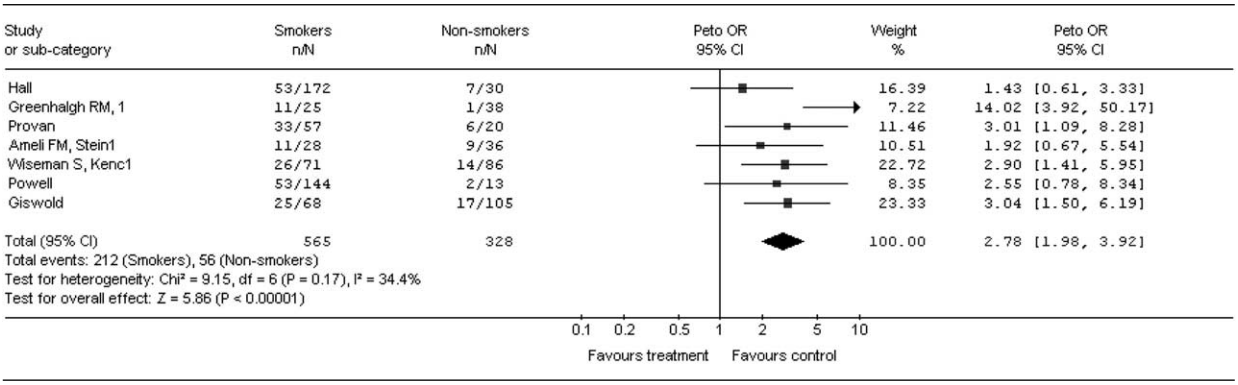
ASV, Autogenous saphenus vein; *P*, polyester, *D*, Dacron; *PTFE*, polytetrafluoroethylene; *NR*, not reported, *NS*, not significant.

Table V. Patency rates in polyester grafts in smokers versus nonsmokers



OR, Odds ratio; *CI*, confidence interval.

Table VI. Patency rates in autogenous grafts in smokers versus non-smokers



OR, Odds ratio; *CI*, confidence interval.

improved ($P = .003$; 95% CI, 79% to 96%). The patency rates in former smokers were comparable with the never smokers group.

DISCUSSION

Patency of grafts in smokers versus nonsmokers. Continued smoking after lower limb bypass surgery results in a threefold increased risk of graft failure and a number needed to harm of only four. This indicates that in smokers, 57% (95% CI, 50% to 64%) of graft failure can be attributed to smoking. The ability of smokers to deceive their doctors about their continued smoking habit may underestimate the true incidence of smokers. One quarter of patients undergoing femoropopliteal bypass surgery are covert

Table VII. Dose response in current, former, and never smokers

Study	*Graft location*	*Patency never smokers N (%)*	*Patency former smokers n (%)*	*Patency smokers n (%)*	P	*Patency*
Prospective						
Robicsek[51]	A-iliac, A-fem	10 (100%)	86 (90%)	44 (<1 pk/d: 85%)	NR	Primary
				18 (>1 pk/d: 69%)	NR	
Retrospective						
King[28]	Ax-fem, Ax-fem-fem	17 (94%)	NR	12 (<15 cig/d: 62%)	<.05	Secondary
				13 (>15 cig/d: 38%)		
Myers[40]	A-fem, Fem-pop, Fem-tib	25 (90%)	32 (<15cig/d:92 %)	110 (<15 cig/d: 75%)	.001	Primary
			50 (>15cig//d:90%)	33 (>15 cig/d: 65%)	.001	
Provan[48]	A-fem	12 (70%)	67 (80%)	130 (46%)	<.001	Primary

A, Aorta; *NR,* not reported.

smokers.[9] Indeed, studies that used biochemical smoking markers to determine the smoking status of the included patients found more outspoken differences in patency rates (relative risk [RR], 3.8) between smokers and nonsmokers than studies that based smoking status solely on the patient responses (RR, 3.1). Because only a minority of the present studies used biochemical makers, it is likely that the true influence of smoking on graft patency is even larger than reported in this analysis.

The effect of smoking on the patency of different graft materials. There was no difference between autogenous or polyester graft patency in smoking patients. This absence of a preference in graft material is not unexpected. In a recent meta-analysis, no clear evidence was present for a possible preference in femoropopliteal graft materials.[64]

Dose response and the effect smoking cessation. Although a dose-response relationship for smoking on graft patency was present, no evidence exists that graft patency is improved by reducing the number of daily cigarettes. Only three studies (one prospective, two retrospective) reported on the subject regarding graft patency by using a questionnaire for the patients' smoking habits. Nevertheless, it is likely that the effect is congruent with other atherosclerotic diseases such as stroke and coronary artery disease, where a clear dose-response exists.[4,65] A possible underreporting by smokers on the duration of smoking and the number of daily cigarettes is indeed more than likely. However, this is a conservative bias, therefore the visible dose-response relationship is valid, although potentially underestimated.

Smoking cessation does seem to bring about a large improvement in graft patency. Most studies reported on smokers who had quit smoking after a peripheral bypass operation. This implicates that smoking cessation, even if started after the operation, benefits graft patency.

Limitations. Although 58 potentially eligible studies were found, only half could be included. The reason for studies not to present separate data on graft patency differences between smokers and nonsmokers could be caused by a tendency not to report nonsignificant findings. This could be a potential source of bias. On the other hand, the consistency of the data and the absence of statistical heterogeneity in the analysis suggest that the effect of this bias is likely to be small.

Future implications. Because the patency outcome differences between smokers and nonsmokers are clearly in favor of the nonsmokers, there should be at least additional patient information before vascular surgery about the consequences of smoking and the subsequent risk of premature graft failure. More important, patients should receive expert help and aid to stop smoking before vascular surgery.

CONCLUSION

Continued smoking after lower limb bypass surgery results in an at least a threefold increased risk of graft failure. Smoking cessation, even if instigated after the operation, restored graft patency towards the patency of never smokers. These results imply that adequate smoking-cessation strategies in patients eligible for lower limb bypass surgery are of the utmost importance.

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