REVIEW ARTICLE

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A meta-analysis to compare Dacron versus polytetrafluroethylene grafts for above-knee femoropopliteal artery bypass

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Background: **Surgical revascularization for lower limb ischemia remains an important component for optimization of quality of life and symptoms in patients with peripheral arterial disease. In the absence of a vein graft, prosthetic alternatives are considered. The objective of this meta-analysis was to establish which prosthetic graft, Dacron or polytetrafluroethylene (PTFE), has the better long-term patency in patients undergoing an above-knee femoropopliteal arterial bypass.**

Methods: **This meta-analysis was performed by use of Cochrane and Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. An electronic search of all relevant databases was performed from 1990 to 2013 with the Medical Subject Headings "Dacron," "polytetrafluroethylene," "PTFE," "above knee," "femoropopliteal," and "bypass" combined with the Boolean operator "AND." The inclusion criteria were randomized controlled trials, use of Dacron vs PTFE prosthetic conduits, and completion of an above-knee femoropopliteal arterial bypass involving adult patients older than 18 years presenting with disabling claudication, rest pain or tissue loss, occlusion of the superficial femoral artery, and reconstitution of the above-knee popliteal artery. Whenever studies included above- and below-knee data, only the above-knee arterial bypass data were extracted and analyzed. Graft patency rates were calculated with RevMan 5.1 software provided by the Cochrane Collaboration.**

Results: **Ninety-one publications were reviewed. After exclusion of duplicate, nonrandomized, and alternative bypass surgery studies, eight randomized controlled trials were identified and included in the meta-analysis. Two of the included trials represented follow-up evaluation of two previous studies, and for the purpose of this analysis, the initial and follow-up studies were subsequently evaluated as one trial. In this meta-analysis, 1192 patients were assessed, including 601 Dacron and 591 PTFE above-knee lower limb arterial bypasses. Primary patency was calculated from all included studies. However, only four studies provided data to evaluate secondary patency. Mean age reported was 66 years. Although all studies described cardiovascular comorbidities and risk factors including myocardial ischemia, diabetes, hypertension, and smoking, exact patient numbers were not consistently provided. Included studies evaluated grafts from 5 to 8 mm. Although primary and secondary patency rates at 12 months were not significantly different (relative risk [RR], 0.78; $P = .08$, and RR, 0.84; $P = .52$), 24-, 36-, and 60-month primary patency rates were significantly better with Dacron compared with PTFE grafts (RR, 0.79; $P = .003$; RR, 0.80; $P = .03$; RR, 0.85; $P = .02$). Statistical analysis also supported higher secondary patency rates for Dacron at 24 months (RR, 0.75; $P = .02$) and 60 months (RR, 0.76-0.77; $P = .03$-.27). Although primary patency was similar between grafts (28% vs 28%; $P = .12$), secondary patencies were better with Dacron at 10 years (49% vs 35%; $P = .01$). Antiplatelet and anticoagulation protocols varied between the trials. There was no difference in amputation, overall morbidity, or mortality rates between the two surgical graft populations.**

Conclusions: **Current evidence suggests that Dacron prosthetic grafts are superior to PTFE grafts in above-knee femoropopliteal arterial bypass procedures. Further randomized trials targeting standardization of confounding variables, particularly graft size and best medical therapy, are warranted. (J Vasc Surg 2014;60:506-15.)**

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Peripheral arterial disease, defined as the presence of atherosclerosis distal to the aortic bifurcation, affects between 12% and 20% of patients older than 60 years, accounting for an estimated 27 million people affected in North America and Europe.[1,2] Claudication is defined as reproducible lower extremity muscle pain reflecting the symptomatic expression of the inability of the lower limb musculature to maintain adequate perfusion and oxygenation during exertional activity. Claudication symptoms progress in 25% of all those affected, with deterioration at rates of 7% to 9% in the first year and then subsequently at rates of 2% to 3% per year. Disease progression to critical limb ischemia may be manifested with rest pain or tissue loss with an incidence of 0.25 to 0.45 per 1000 people per year.[3]

Although endovascular modalities are increasingly used, surgical revascularization for lower limb ischemia still remains an important component for optimization of quality of life and symptoms in those patients with claudication while preventing tissue or limb loss in more advanced cases of critical limb ischemia. Myriad different bypass conduits, including autologous, homologous, and prosthetic grafts, are currently available. Superiority of vein graft is well established and remains the "gold standard" conduit for vascular reconstruction.[4-6] The Cochrane review by Twine and McLain[7] in 2010 reported better primary patency rates with autologous vein compared with polyester (Dacron), polytetrafluroethylene (PTFE), and human umbilical vein for above-knee femoropopliteal arterial bypass grafts.

However, despite the advantages of autologous vein, a prosthetic graft may be considered an alternative in the absence of a suitable vein conduit or in the presence of certain patient comorbidities. Although previous studies have reported the efficacy of above-knee prosthetic arterial bypass grafts, few have specifically compared the different prosthetic materials, addressed long-term prosthetic graft patency rate and limb salvage outcomes, or provided strict protocols for best medical therapy, especially the role of antiplatelet and anticoagulation therapy. Indeed, Twine and McLain[7] have suggested a requirement for more randomized data to explore actual improvements in limb salvage for each of the prosthetic bypass conduits. A definitive consensus regarding the role and type of prosthetic graft for above-knee arterial bypass remains unclear. The main objective of this meta-analysis and systematic review was to investigate long-term patency of Dacron and PTFE prosthetic grafts after above-knee femoropopliteal arterial bypass.

METHODS

This meta-analysis was performed by use of standard guidelines outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (version 5.1.0) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[8,9]

Search strategy and study selection. The authors performed the literature search with the following electronic resources: PubMed, Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov. The search was completed with the Medical Subject Headings "Dacron," "polytetrafluroethylene," "PTFE," "above knee," "femoropopliteal," and "bypass" combined with the Boolean operator "AND." We did not apply language limitations to our search. The authors considered all studies published from 1990 to 2013. Potentially relevant publications and comparative studies of Dacron vs PTFE were retrieved. We have also reviewed references of all comparative research to identify any further potential studies, which were subsequently evaluated.

Inclusion and exclusion criteria. The inclusion criteria for this meta-analysis were randomized controlled trials, use of Dacron vs PTFE prosthetic conduits, and completion of an above-knee femoropopliteal arterial bypass involving adult patients older than 18 years presenting with disabling claudication, rest pain or tissue loss, occlusion of the superficial femoral artery, and reconstitution of the above-knee popliteal artery. We also included lower limb arterial bypass studies when we were able to extract data for supragenicular bypass. Nonrandomized clinical trials or other comparative studies and research assessing other conduits for above-knee femoropopliteal artery bypass or more distal arterial bypasses were excluded from further analysis, as were patients with a history of previous femoropopliteal bypass, less than 1 year of life expectancy, lower extremity oncologic treatment with radiotherapy or chemotherapy, and no valid informed consent documentation.

Data extraction. All data were extracted independently by two authors (I.J.R. and P.D.) by a specifically designed data collection pro forma that allowed a list of all relevant information from each study, including the year of publication, study design, inclusion criteria, exclusion criteria, type of graft used, number of participants in each group, patency rates, use of antiplatelet and anticoagulant therapy, and failure of procedures. The primary outcomes for this meta-analysis included primary and secondary graft patency rates at 12 months, 24 months, 36 months (primary only), 5 years, and 10 years. Secondary outcome measures included an assessment of antiplatelet and anticoagulation strategies, limb loss rates, and overall morbidity and mortality.

Assessment of risk of bias. The Cochrane Collaboration's tool for assessing risk of bias was used to assess the quality of the randomized controlled trials included in this meta-analysis independently by two raters (I.J.R. and P.D.).[8] This included random sequence generation; allocation concealment; blinding; and assessment of outcome, incomplete data, selective reporting, and other sources of bias.

Statistical analysis. The meta-analysis was performed with the RevMan 5.2 tool provided by the Cochrane Collaboration (http://ims.cochrane.org/revman). All the assessed variables were dichotomous. Statistical analysis was performed by the Mantel-Haenszel test. We used risk ratio (RR) as the summary statistic with corresponding 95% confidence intervals (CIs). Pearson χ^2 test was used to assess statistical heterogeneity where significance was set at

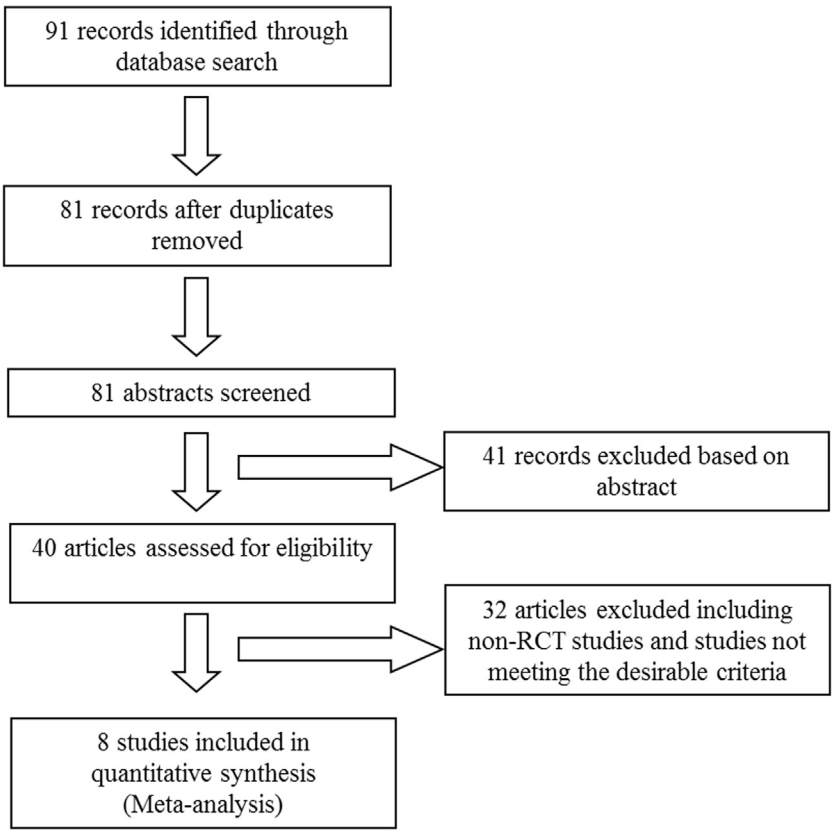

Fig 1. Study flow diagram according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. *RCT,* Randomized controlled trial.

a P value $< .10$ and quantified by measuring I^2. An I^2 value above 50% indicated important statistical heterogeneity. The random-effects model was then employed when there was significant heterogeneity. The meta-analysis was completed with a fixed-effects model and a random-effects model for each outcome. These analyses were subsequently compared, and where there was no difference between the two, we used the fixed-effects model. Both models were presented if there was inconsistency between results. A P value $< .05$ was considered statistically significant.

RESULTS

After review of all relevant literature by use of the PRISMA guidelines,[9] eight randomized controlled trials were identified and included in the meta-analysis (Fig 1 and Table).

Patient demographics

In this meta-analysis assessing Dacron vs PTFE grafts for above-knee lower limb arterial bypasses, 1192 patients were subsequently included; 601 underwent procedures with Dacron, and 591 were treated with PTFE grafts. Mean age reported was approximately 66 years.[10-15] Although exact comorbidity data could not be further analyzed in this meta-analysis because of inconsistencies in the included studies, it is recognized that most studies included a patient population with generalized cardiovascular comorbidities and risk factors including myocardial ischemia, diabetes, hypertension, and smoking.[10-17]

Graft type

Davidovic et al[10] compared the use of 8-mm collagen-coated Dacron with 8-mm expanded PTFE grafts for above-knee femoropopliteal arterial bypasses. van Det et al[11] assessed the long-term patency of 6-mm collagen-impregnated Dacron and expanded PTFE vascular grafts, whereas Jensen et al[12] compared 6-mm gelatin-coated Dacron and expanded PTFE grafts for patients undergoing above-knee femoropopliteal arterial bypass for chronic lower limb ischemia. Post et al[13] assessed patency of unsealed knitted polyester velour grafts and thin-walled PTFE grafts for above-knee surgery with diameter ranging from 6 to 8 mm. Devine et al[14,15] compared collagen-coated heparin-bonded Dacron and PTFE. Although the authors used predominantly 6-mm grafts, they did not specify exact patient numbers. Abbott et al[16] and Green et al[17] investigated patency rates between collagen-impregnated Dacron and expanded PTFE grafts used for above-knee femoropopliteal arterial reconstructions in patients with arteriographically proven occlusion of the superficial femoral artery and reconstitution of the popliteal artery above the knee. However, the decision pertaining to the size of the graft was left to the

operating surgeon; graft sizes varied between 5 and 8 mm. In summary, three of the included studies compared the same size of prosthetic graft type as stated in the original clinical trial study protocol. Two studies evaluated 6-mm grafts, and one study assessed 8-mm grafts; in the other study, the graft size ranged between 5 and 8 mm.

Operative data

The most recent study by Davidovic et al[10] assessed 85 patients with disabling claudication and critical ischemia who were recruited to a bicenter randomized controlled trial directly comparing 8-mm collagen-coated Dacron (n = 42) with 8-mm expanded PTFE (n = 43) for above-knee femoropopliteal grafts. The main indication for surgery was critical limb ischemia, which occurred more commonly in the Dacron group (71.4% vs 69.7%). At 12-month follow-up, primary graft patency was significantly better in the Dacron group (100%) compared with the PTFE group (88.4%) ($P <$ .05). However, there was no difference in secondary graft patency rates (83.3% vs 75%; $P >$ .05). There was no information as to whether any additional vascular procedures were performed during the main surgery. Additional findings from their study suggested that single-vessel crural runoff significantly reduced prosthetic graft patency, more so in the Dacron group than in the PTFE group ($P <$ .05).

van Det et al[11] assessed the long-term patency of 6-mm collagen-impregnated Dacron (n = 114) and expanded PTFE (n = 114) vascular grafts used during standardized above-knee femoropopliteal arterial bypasses performed for disabling claudication, rest pain, or tissue loss. These authors did not report any significant difference in relation to indications for surgery for the two graft groups ($P =$ .94). There was no comment on additional procedures performed during the main surgical procedure. They reported significantly higher 5-year primary and secondary graft patencies for the Dacron grafts compared with PTFE (52% vs 36%, $P =$ .04 and 70% vs 51%, $P =$ .01). However, primary patency for the groups appeared to converge at 10-year follow-up despite maintenance of improved secondary patency for the Dacron group (49% vs 35%; $P =$ .01).

Jensen et al[12] published a series of 427 randomized patients undergoing above-knee femoropopliteal arterial bypass for chronic lower limb ischemia with 6-mm gelatin-coated Dacron (n = 208) or 6-mm expanded PTFE (n = 205) grafts. One patient did not proceed to surgery, whereas 13 others were excluded because of randomization errors, missing postoperative data, or absence of valid patient identification data. Primary and secondary graft patencies at 24 months were significantly better in the Dacron group than in the PTFE group (70% vs 57%, $P =$ .02 and 76% vs 65%, $P =$ .04). These authors reported a trend toward better patency in claudicants compared with critically ischemic patients (65% vs 59%; $P =$ not significant). The authors did not comment on concomitant procedures. Subgroup analysis suggested that the number of patent runoff vessels influenced midterm patency rates. Patients with more than one crural vessel performed better than those with only one patent runoff vessel (67% vs 50%; $P =$ .01).

Devine et al[14,15] assessed 209 patients who were followed up for a period of at least 5 years. Results were reported in two separate publications. As these authors included both above- and below-knee procedures, specific analysis was not possible, but we were able to extract the data for supragenicular surgery and to assess primary patency. Ninety-one patients underwent above-knee surgery with use of Dacron graft, and 88 had a PTFE prosthesis. There was no comment on additional recanalization procedures. Secondary patency and other outcomes were presented for the overall population; therefore, we did not include these data because our main focus was above-knee surgery. *P* values were not available for 12- and 24-month follow-up. Follow-up at 36 months revealed significantly better patency of Dacron material ($P =$ .037). Five-year primary patency for the Dacron and PTFE groups was 50% vs 41% ($P =$ .14).

Post et al[13] investigated patency of Dacron and thin-walled PTFE for above-knee grafts in 203 patients. This study also included below-knee procedures. Therefore, as for the studies of Devine et al,[14,15] we had to extract the above-knee data to perform our meta-analysis. Seventy-six patients received Dacron and 65 had PTFE grafts. Subgroup analyses of primary patency for supragenicular procedures were 80% vs 71%, 75% vs 65%, and 70% vs 62% at 12, 24, and 36 months of follow-up for the Dacron and PTFE groups ($P =$ .35). Although study inclusion allowed any type of inflow reconstruction, exact specifics were not detailed. We were unable to comment on secondary patency as this result was given for the overall group.

Further published studies have failed to elicit any difference between the two prosthetic conduits. Abbott et al[16] and Green et al[17] investigated patency rates between collagen-impregnated Dacron and expanded PTFE grafts used for above-knee femoropopliteal arterial reconstructions in patients with arteriographically proven occlusion of the superficial femoral artery and reconstitution of the popliteal artery above the knee. Eligible patients with claudication, rest pain, or ischemic tissue loss were enrolled between 1991 and 1996. Critical limb ischemia was an indication in 38% of the Dacron population and in 37% of the PTFE group, and the authors commented that this difference was not significant (no *P* value available). The operator determined graft diameter and postoperative anticoagulation regimen. Iliac angioplasty and iliofemoral bypasses were permitted as an additional procedure. This multicenter randomized trial did not demonstrate any significant difference between the grafts for 3-year primary patency rates (62% vs 58%; *P* value not stated) and overall secondary patency rates (75% vs 75%; *P* value not stated). There was also no significant difference at 5-year follow-up, when primary patency was 45% for Dacron and 43% for PTFE. Similarly, there was no difference in secondary patency, which was 68% in both groups. Interestingly, subgroup analyses suggested that smaller graft sizes of 5 or 6 mm were significant predictors of graft occlusion ($P =$ .0006). This

Table. Details of randomized controlled trials included in meta-analysis

Author, date, and country	*Patient group*	*Type of study*	*Outcomes*	*Key results Dacron vs PTFE*	*Notes*
Davidovic et al,[10] 2010 Serbia	85 patients with disabling claudication or critical limb ischemia suitable for above-knee reconstruction were randomized to Dacron (n = 42) and expanded PTFE (n = 43).	Prospective randomized clinical trial	Primary graft patency Secondary graft patency	100% vs 88.37% ($P < .05$) 83.3% vs 75% ($P > .05$)	This study suggested that primary patency might be better for the Dacron grafts. However, in patients with only one patent crural vessel, the authors noticed decreased patency of both grafts and favored the use of PTFE graft ($P < .05$) There was no significant difference in secondary patency between groups. All patients received aspirin postoperatively.
van Det et al,[11] 2009 The Netherlands	228 patients were randomly allocated to expanded PTFE group (n = 114) and Dacron group (n = 114). Patients presenting with disabling claudication, rest pain, or tissue loss who underwent above-knee arterial bypass were included.	Prospective randomized clinical trial	Primary graft patency Secondary graft patency	At 2 years: 70% vs 64% ($P = .38$) At 5 years: 52% vs 36% ($P = .04$) At 10 years: 28% vs. 28% ($P = .12$) At 2 years: 84% vs 78% ($P = .31$) At 5 years: 70% vs 51% ($P = .01$) At 10 years: 49% vs 35% ($P = .01$)	The authors of this study followed up the patients for the longest time. They used the same size graft in both groups. The 5-year patency was significantly better in the Dacron group, in primary as well as in secondary patency patients. The 10-year follow-up revealed similar primary patency in both groups; however, secondary patency was again significantly better in the Dacron group. All patients were prescribed warfarin after surgery.
Jensen et al,[12] 2007 Denmark	427 patients presenting with chronic lower limb ischemia were included in this study; 208 patients were randomized to Dacron group, 205 to PTFE group; 14 were excluded.	Prospective randomized clinical trial	Primary graft patency Secondary graft patency	At 2 years: 70% vs 57% ($P = .02$) At 2 years: 76% vs 65% ($P = .04$)	This study showed superiority of Dacron graft vs PTFE in patients after above-knee femoropopliteal bypass. The authors also found that the number of outflow vessels had a significant impact on the graft patency; 67% of patients with more than one crural vessel had patent graft ($P = .01$).
Abbott et al,[16] 1997 Green et al,[17] 2000 United States	244 patients were randomized. Sufficient data were available for 231 patients presenting with claudication, ischemic rest pain, or tissue loss.	Prospective randomized clinical trial	Primary graft patency Secondary graft patency	(P values not significant, exact value not available for all data sets) At 1 year: 74% vs 76% At 2 years: 63% vs 65% At 3 years: 62% vs 58% At 5 years: 45% vs 43% (P value not significant, exact value not available) At 1 year: 88% vs 88% At 2 years: 80% vs 80% At 3 years: 75% vs 75% At 5 years: 68% vs 68%	This trial did not demonstrate any significant difference in graft patency between the two groups. Patients underwent supragenicular procedures only. There was no determined graft size. The authors reported that a small graft size (5-6 mm) was a significant predictor of graft failure ($P = .0006$) The study by Green et al added 5-year follow-up results. No details are available on anticoagulation therapy.

Table. Continued.

Author, date, and country	*Patient group*	*Type of study*	*Outcomes*	*Key results Dacron vs PTFE*	*Notes*
Post et al,[13] 2001 Germany	203 patients were randomized in total. These included above- and below-knee bypasses. Data were extracted for above-knee patients and included 76 patients who had Dacron prosthesis and 65 who had PTFE.	Prospective randomized clinical trial	Primary graft patency	(*P* value not available for all of the data as patency rates were extracted from overall results; however, it was commented as not significant.) At 1 year: 80% vs 71% At 2 years: 75% vs 65% At 3 years: 70% vs 62% ($P = .35$)	The study by Post et al did not show statistically significant differences between both groups. However, these included above- and below-knee bypasses. We were able to extract data for above-knee bypasses, for which the authors did not find significant differences in graft patency between the two surgical grafts. Multivariate analysis revealed that below-knee anastomosis was the independent predicting factor of primary graft failure (RR, 1.7; CI, 1.05-2.8). Impaired secondary patency was associated with a below-knee bypass RR of 3.3 (CI, 1.8-6.3) and distal gangrene RR of 2.0 (CI, 1.01-3.8; $P = .048$). Major amputation was predicted by infragenicular bypass, tissue necrosis, and poor runoff. Postoperatively, patients received antiplatelet therapy, heparin, or warfarin. This was not standardized.
Devine et al,[14,15] 2001, 2004 United Kingdom	209 patients were randomized to receive bypass surgery. The study included above- and below-knee procedures. Data were extracted for above-knee surgery to allow statistical analysis. This included 91 heparin-bonded Dacron prostheses and 88 PTFE grafts.	Prospective randomized controlled trial	Primary graft patency	(*P* value not available for all the data patency rates were extracted from overall results; however, it was commented as not significant.) 1 year: 76% vs 66% 2 years: 65% vs 52% 3 years: 61% vs 46% ($P = .037$) 5 years: 50% vs 41% ($P < .142$)	Devine et al published their results in two data sets. They reported significantly better patency rates with Dacron than with PTFE at 3 years ($P < .044$), but the difference was no longer statistically significant at 5 years ($P < .055$). Major limb amputation was higher ($P < .025$) in the PTFE group compared with the Dacron group at 3 and 5 years of follow-up. These results apply to overall data, which include above- and below-knee data. All patients received 300 mg of aspirin postoperatively unless contraindicated. There was no comment on alternative treatment if this was the case.

CI, Confidence interval; *RR,* relative risk; *PTFE,* polytetrafluoroethylene.

was also a case for patients younger than 65 years ($P = .001$).

Primary outcome measures

Primary patency rates at 12 months. Primary patency rates at 12 months were documented in four studies; Davidovic et al reported a significant advantage with Dacron, whereas Abbott/Green et al, Post et al, and Devine et al did not show statistically significant difference between the two prosthetic conduits.[10,14-17] Our meta-analysis revealed low heterogeneity ($I^2 = 31\%$) between these studies, and therefore a fixed-effects model

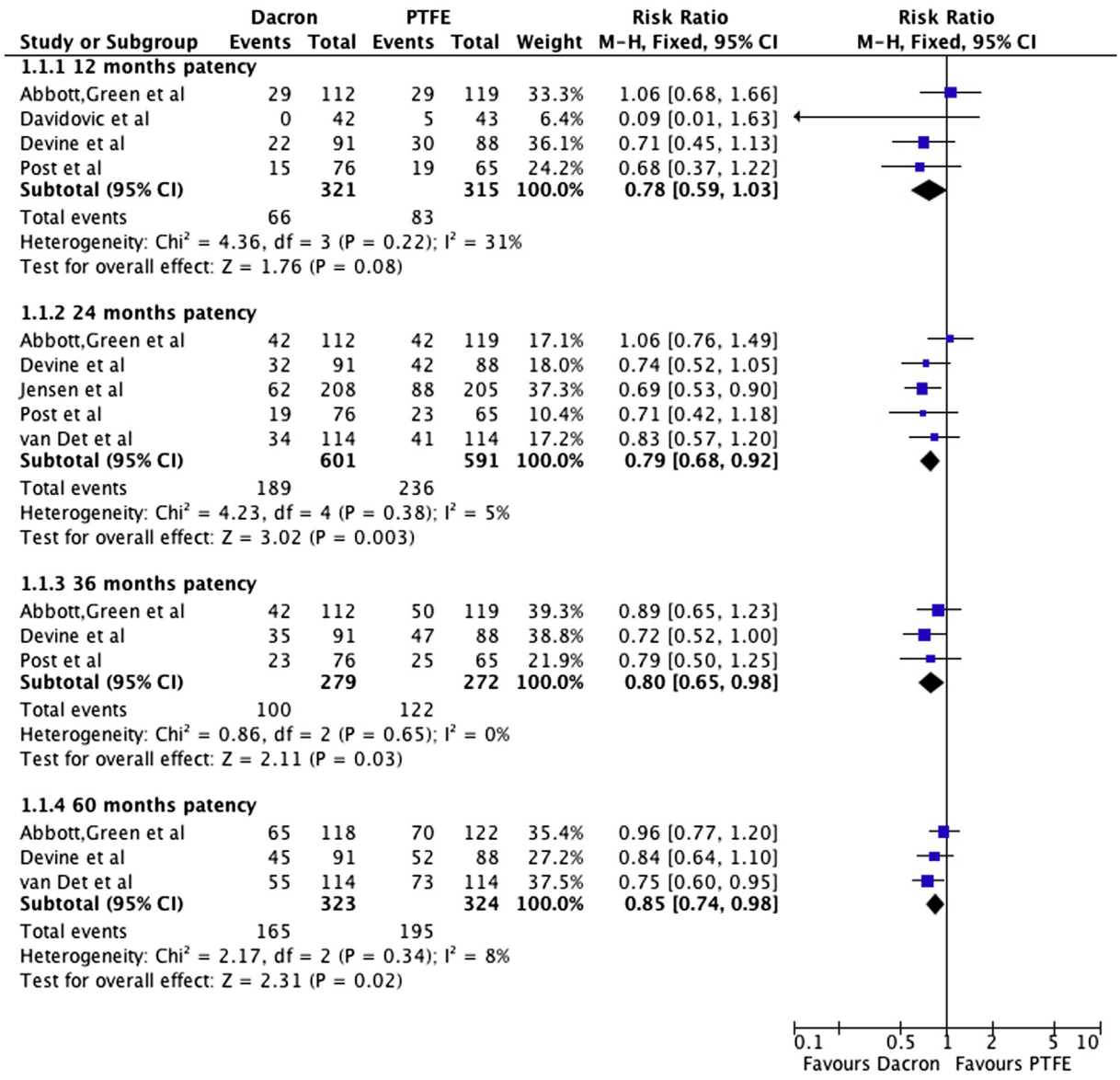

Fig 2. Meta-analysis of primary patency rates for 12, 24, and 36 months and 5 years by fixed-effects Mantel-Haenszel (*M-H*) model. *CI,* Confidence interval; *PTFE,* polytetrafluoroethylene.

was used that showed a trend toward better patency in the Dacron group, which did not reach significant difference (RR, 0.78; 95% CI, 0.59-1.03; $P = .08$) (Fig 2).

Primary patency rates at 24 months. Patency rates at 24 months were described in five of the randomized controlled trials reviewed. Jensen et al and van Det et al reported better patency with Dacron, whereas Abbott/Green et al, Post et al, and Devine et al identified no significant difference between Dacron and PTFE.[11-17] Fixed model results due to absence of heterogeneity from our meta-analysis revealed a significant difference in favor of the Dacron graft (RR, 0.79; 95% CI, 0.68-0.92; $P = .003$) (Fig 2).

Primary patency rates at 36 months. Patency results at 36 months were published in three studies.[14-17] Abbott/Green et al and Post et al did not show significant differences between the two graft materials. Devine et al revealed significantly better performance with the Dacron graft (61% vs 46%; $P = .037$). Fixed model results showed significantly better outcome in the Dacron group (RR, 0.80; 95% CI, 0.65-0.98; $P = .03$) (Fig 2).

Primary patency rates at 5 and 10 years. van Det et al, Devine et al, and Abbott/Green et al reported 5-year primary patency rates.[11,14-17] Only the first one of this group showed significantly improved patency rates of Dacron compared with PTFE (52% vs 36%; $P = .04$). The remaining studies did not show significant differences. Patency reported in the study of Abbott/Green et al was 45% vs 43% (*P* value stated as not significant), whereas

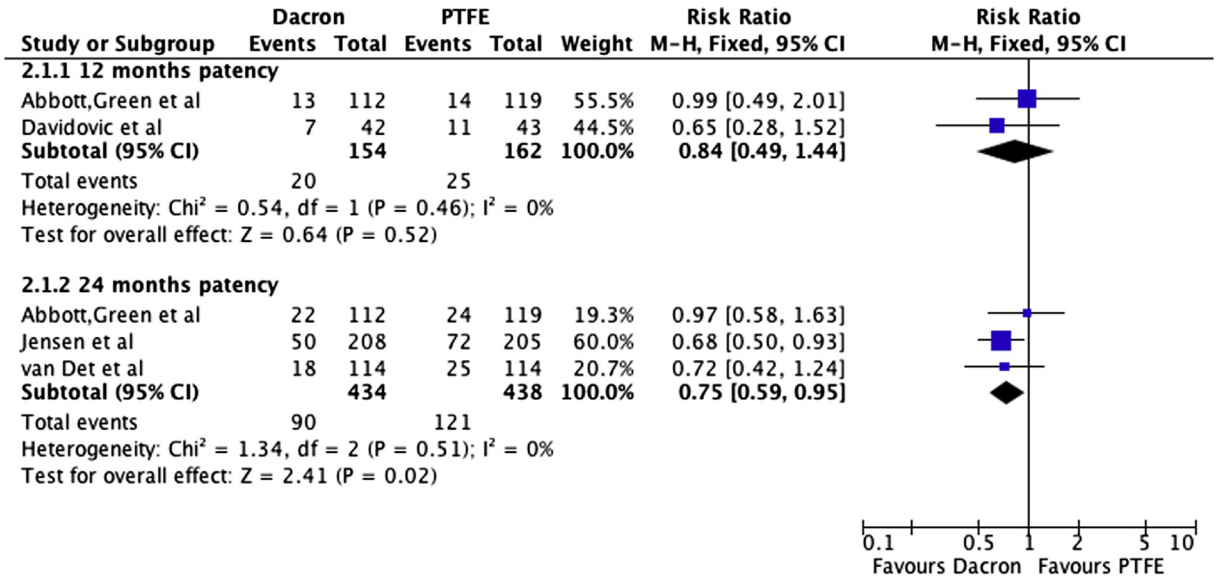

Fig 3. Meta-analysis of secondary patency rate for 12 and 24 months by fixed-effects Mantel-Haenszel (*M-H*) model. *CI,* Confidence interval; *PTFE,* polytetrafluoroethylene.

Devine et al reported a 50% patency with Dacron vs 41% for PTFE ($P < .142$). Our meta-analysis, however, revealed a significant advantage with Dacron (RR, 0.85; 95% CI, 0.74-0.98; $P = .02$) (Fig 2). van Det et al also reported no significant difference in primary patency rate between graft types at 10 years (28% vs 28%; $P = .12$).

Secondary patency. Secondary patency rates were calculated for only five of the included studies.[10-12,16,17] Three publications that included below-knee procedures presented only combined patency data inclusive of above- and below-knee procedures.[13-15]

Secondary patency rates at 12 months. Davidovic et al and Abbott/Green et al described 12-month secondary patency rates.[10,16,17] Our meta-analysis did not show a statistically significant difference between the two graft materials (RR, 0.84; 95% CI, 0.49-1.44; $P = .52$) (Fig 3).

Secondary patency rates at 24 months. Three randomized controlled trials by van Det et al, Jensen et al, and Abbott/Green et al assessed secondary patency at 24 months.[11,12,16,17] Statistical analysis supports a higher patency rate for Dacron compared with PTFE grafts (RR, 0.75; 95% CI, 0.59-0.95; $P = .02$) (Fig 3).

Secondary patency rates at 5 and 10 years. van Det et al[11] reported a significant benefit in secondary patency at 5 years with Dacron grafts (70% vs 51%; $P = .01$). Abbott/Green et al[16,17] did not see this difference in their study, in which reported patency was 68% for both materials (P value stated as not significant). Our meta-analysis suggested significant heterogenicity between these studies, and therefore we present both fixed and random model results, which identified a significant benefit with Dacron (RR, 0.76; 95% CI, 0.59-0.97; $P = .03$) in the former analysis and no difference in the latter analysis (RR, 0.77; 95% CI, 0.43-1.23; $P = .27$) (Fig 4). van Det et al[11] demonstrated continued secondary patency superiority with Dacron at 10-year follow-up as well (49% vs 35%; $P = .01$).

Secondary outcome measures

Antiplatelet and anticoagulation treatment. Antiplatelet and oral anticoagulation therapies were administered in 82% and 3% of postoperative patients by Jensen et al.[12] In the study by van Det et al,[11] all patients were prescribed warfarin postoperatively, although there is no comment on follow-up or monitoring. Devine et al[14,15] administered 300 mg of aspirin. No specified antiplatelet therapy, heparin, or warfarin was used by Post et al.[13] Davidovic et al[10] used aspirin in their patients. Abbott/Green et al[16,17] deferred the decision pertaining to the use of antiplatelet or anticoagulation therapy to the operating surgeon. Unfortunately, secondary prevention in the included studies varied and did not permit further analysis.

Limb loss. Davidovic et al[10] documented seven amputations at the end of their follow-up, with no significant difference between the grafts ($P > .05$). All amputations were performed in patients who required lower limb revascularization for critical ischemia. van Det et al[11] reported seven above-knee (PTFE = 3) and nine below-knee (PTFE = 4) amputations after a 10-year follow-up period. Thirteen major limb amputations were reported by Jensen et al,[12] in which there was no statistical significance between types of graft used (Dacron = 7). However, these authors noted that surgical revascularization for critical ischemia significantly related to amputation rates ($P < .001$). Abbott/Green et al[16,17] described 10 patients (4%) who proceeded to major limb amputation, five in each group. However, only one patient required amputation for graft failure, whereas all other patients required amputation for uncontrollable local sepsis despite a patent graft. As the

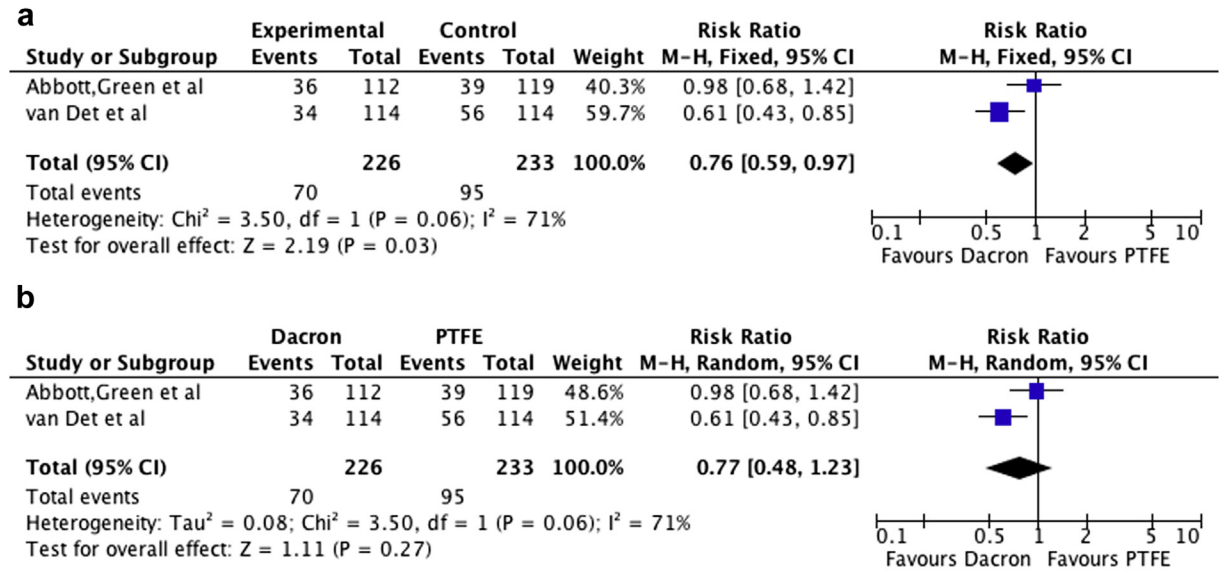

Fig 4. Meta-analysis of 5-year secondary patency rate by fixed-effects **(a)** and random-effects **(b)** Mantel-Haenszel (*M-H*) models. *CI,* Confidence interval; *PTFE,* polytetrafluoroethylene.

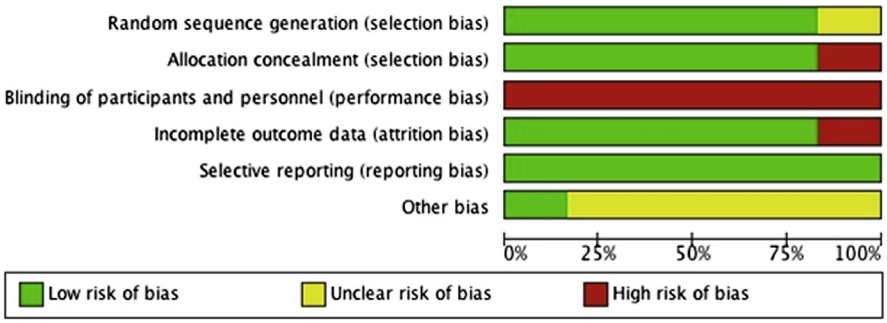

Fig 5. Risk of bias assessment.

remaining studies included below-knee data, we were not able to comment on limb loss.[13-15]

Morbidity and mortality. Abbott/Green et al[16,17] documented a 6.5% overall complication rate, with cardiac morbidity accounting for 2.2%. There was no perioperative mortality, and 3-year survival was 77%. This reduced to 59.4% during 5-year follow-up. There was no difference in morbidity or mortality between the two graft conduits. Jensen et al[12] described a 13% morbidity rate related mainly to superficial wound complications (necrosis, oozing, or hematoma) and a 0.7% perioperative and 9% 2-year mortality rate. There was no significant difference in mortality and wound, cardiac, or pulmonary complications between the two grafts ($P = .22$). van Det et al[11] showed a 12.8% 2-year, 32.0% 5-year, and 60.7% mortality at the end of the 10-year follow-up period for their cohort of patients. Although there was no in-hospital mortality, two patients died within 30 days of surgery. No other complications were documented, and there were no differences in these outcomes between the two graft materials. Davidovic et al[10] did not report any morbidity or mortality data. As previously stated, the remaining studies included below-knee procedures, and therefore we could not analyze their data.

DISCUSSION

Current evidence confirms that vein graft, when it is available, is a superior choice for lower extremity arterial bypass. Among published reports, no consensus currently exists on which type of prosthetic graft is better, and the surgeon's subjective preference or previous experience would most likely be the reason for use of one graft over another. A Cochrane review in 2010 suggested that Dacron grafts are at least comparable to PTFE or may even be superior when directly compared. Since that publication, new evidence has emerged in support of the Dacron graft.[10] Some authors have also recommended use of a vein cuff together with prosthetic material to improve longer term patency. However, the randomized controlled trial of Griffiths et al[18] comparing PTFE grafts with and without vein cuff did not reveal significant differences in the long-term patency between those groups for

above-knee bypasses. There are no trials reporting the use of vein cuffs with Dacron grafts.

There remains significant heterogeneity between all included studies in our meta-analysis, particularly relating to the patient population and indication for intervention, standardized surgical technique, uniform graft size and material for both conduits, and incorporation of best medical therapy, especially antiplatelet or anticoagulation therapies. Standardization of an end conclusion is therefore challenging because of these possible confounding factors, which introduce bias and affect the strength of concluding remarks. We have also included extracted data in relation to above-knee procedures from three of the included publications, which permitted primary patency analysis. However, we could not evaluate the impact of graft choice on mortality, morbidity, or limb loss rates.[13-15]

Three of the included studies support the use of Dacron graft rather than PTFE in above-knee bypass procedures.[10-12] Devine et al[14,15] further support the use of Dacron grafts at 36 months. These studies are also the most recently reported in the current literature. The 1-, 2-, and 5-year primary patency rates described in the recent publications show superiority of the Dacron graft, with additional advantageous secondary patency rates for the Dacron grafts. Unfortunately, the exact influence of best medical therapy, particularly antiplatelet and anticoagulation therapy, remains unclear, whereas exact anatomic data pertaining to vessel runoff were also lacking in many of the studies. The remaining studies, which reported no significant difference between the two materials, included different graft sizes and variable anticoagulation strategies without strict monitoring.[13,16,17] The effect of newer heparin-bonded graft conduits has also not been fully evaluated by this meta-analysis.

Risk of bias assessment. Selection of patients and allocation were satisfactory in 75% of the studies. However, blinding did not take place in any of the studies included in this meta-analysis. Only Abbott/Green et al[16,17] did not include complete follow-up data, in which 13 patients were lost to follow-up and there was no clear reason provided for their exclusion. Other potential source of bias included antithrombotic strategies, which varied between the centers and the studies included in this meta-analysis (Fig 5).

CONCLUSIONS

Despite inherent limitations due to the quality of the included studies evaluated, our meta-analysis strongly supports use of Dacron grafts over PTFE for above-knee femoropopliteal arterial bypasses. Further randomized trials targeting standardization of confounding variables, particularly graft size and best medical therapy, are warranted.

AUTHOR CONTRIBUTIONS

Conception and design: IR, MO
Analysis and interpretation: IR, PD, MO
Data collection: IR, PD
Writing the article: IR, MO
Critical revision of the article: IR, PD, JM, MO
Final approval of the article: IR, MO
Statistical analysis: IR, MO
Obtained funding: Not applicable
Overall responsibility: MO

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