Table 3 Long-Term Outcomes

	Control (n=52)	PPI (n=55)	p value
Follow-up period (months)	29.6±16.8	31.6±18.1	NS
Fontaine grade at follow-up	2.12±0.18	2.18±0.60	NS
I	0 (0%)	5 (9.1%)	
II	48 (92.4%)	43 (78.2%)	
III	2 (3.8%)	1 (1.8%)	
IV	2 (3.8%)	6 (10.9%)	
ABI at follow-up	0.60±0.19	0.61±0.17	NS
Patients with any events	24 (46.2%)	38 (69.1%)	<0.05
Death from any cause	3 (5.8%)	3 (5.5%)	NS
Amputation	2 (3.8%)	3 (5.5%)	NS
Re-hospitalization related to PAD	8 (15.4%)	29 (52.7%)	<0.001
Bypass surgery	2	5	
PPI	5	15	
Medical therapy	1	9	
New onset of CAD	13 (25.0%)	16 (29.1%)	NS
New onset of CVD	9 (17.3%)	6 (10.9%)	NS

PAD, peripheral artery disease. Other abbreviations see in Table 2.

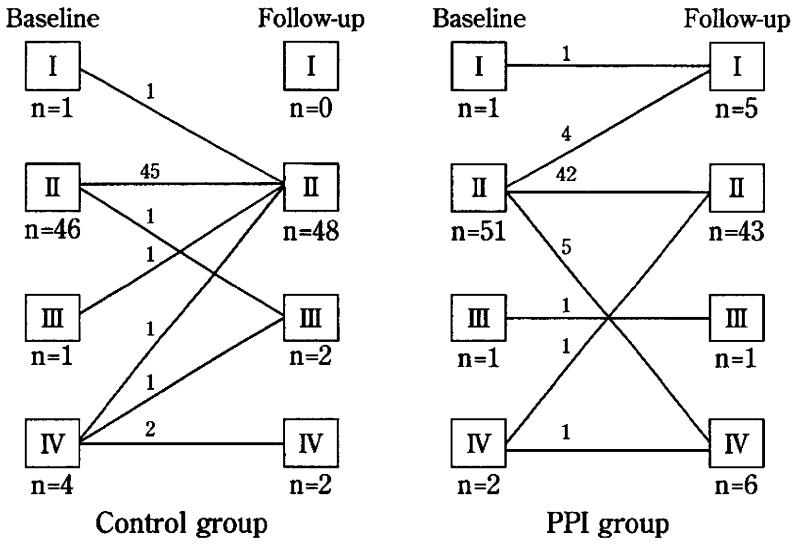

Fig 2. Fontaine grade at baseline and at the last follow-up. PPI, percutaneous peripheral intervention.

(p<0.001), which was also higher than that of the control group (0.61±0.17, p<0.001) (Table 2).

Long-Term Outcomes

Long-term outcomes of patients in both groups are shown in Table 3. The average follow-up periods were 30.6±17.7 months for all patients; 31.6±18.1 months for the PPI group and 29.6±16.8 months for the control group (p=NS). Five patients (9.1%) in the PPI group showed no limb symptoms at follow-up (including 1 patient who had been asymptomatic before PPI), whereas all the control group patients had limb symptoms. On the other hand, 6 (10.9%) of the PPI patients showed ischemic skin ulcer/gangrene at follow-up; 5 of the 6 had been at Fontaine grade II at baseline, and in 2 of these 5 patients PPI was unsuccessful due to distal embolization and perforation. In contrast, in the control group only 2 patients showed such ischemic skin lesions at follow-up. Both of these patients had these lesions at baseline (Fig 2). As a result, the average Fontaine grade at follow-up was not different between the PPI and control groups (2.18±0.60 vs 2.12±0.18, p=NS). The finding that patients receiving PPI showed no long-term improvement in the Fontaine grade compared with medical treatment was further supported by the results of the ABI measurements. At follow-up, ABI of the PPI group returned to the baseline level from 0.81±0.20 to 0.61±0.17, and no statistically significant differences were observed between the PPI and control groups (0.60±0.19, p=NS).

Overall, long-term adverse events were more frequent in the PPI group than the control group. Specifically, adverse events were observed in 69.1% (ie, 38/55) of PPI patients compared with 46.2% (ie, 24/52) of control patients (p< 0.05). The increased number of adverse events observed in the PPI group was mainly due to a high frequency of re-hospitalization due to worsening of limb symptoms (52.7% [ie, 29/55] vs 15.4% [ie, 8/52], p<0.001). Among 29 re-hospitalized patients from the PPI group, 15 patients received repeat PPI and 5 had bypass surgery. Restenosis was observed in 36% (18/50) of patients who underwent successful PPI (32.5% [ie, 13/40] after balloon angioplasty and 50% [ie, 5/10] after stent implantation); all 18 patients were re-hospitalized. In the control group, among the 8 patients who were re-hospitalized, 5 patients received PPI and 2 underwent bypass surgery. Fig 3 shows the Kaplan–Meier survi-

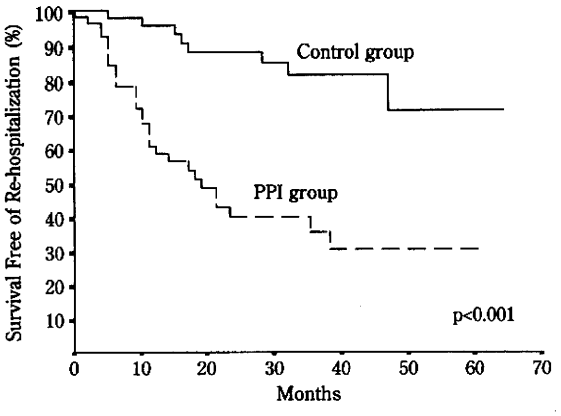

Fig 3. Kaplan–Meier survival curve of patients free from re-hospitalization. The estimated survivals free from re-hospitalization in patients receiving medical therapy (control group: solid line) and percutaneous peripheral intervention (PPI group: broken line) were 95.6% compared with 60.9% at 1 year; and 88.1% compared with 40.0% at 2 years, respectively.

val curve free from re-hospitalization. The survival rate was significantly higher in the control group (solid line) than the PPI group (broken line) ($p<0.001$). The estimated survivals free from re-hospitalization in the control and PPI groups were 95.6% compared with 60.9% at 1 year; and 88.1% compared with 40.0% at 2 years, respectively. Frequencies of death, limb amputation, new onset of coronary artery disease, and new onset of cerebrovascular disease were not statistically different between the 2 groups.

Discussion

Patients with SFA occlusive disease have undergone a shift in management to include PPI as a primary treatment strategy[9,11,12,14–16] Yet, there are no data showing that PPI provides lasting benefit that is superior to conservative medical therapy.

PPI has been shown to provide an excellent short-term outcome in patients with SFA occlusive disease. The technical success rate of PPI for femoropopliteal artery stenoses exceeds 90% (range, 73–100%)![17] Even for chronic total occlusions, advances in technology have provided high recanalization rates (range, 68–83%)![18] However, long-term patency of balloon-dilated lesions is suboptimal. For example, Muradin et al recently reported the results of a meta-analysis showing that the combined 3-year patency rates after balloon dilation for femoropopliteal lesions was 61% for patients with stenoses and claudication, 43% for those with stenoses and critical limb ischemia, and 30% for those with occlusions and critical limb ischemia![19] The 3-year patency rates after stent implantation were similar, ranging from 63% to 66%, and were independent of clinical indication and types of lesions![19] The short- and long-term results of PPI in the present study are comparable to these previous studies. Procedural success was achieved in >90% of patients, and ABI increased by >30%. Restenosis, however, developed in as many as 36% of patients, reducing the long-term success of PPI. As a result, no long-term benefits, including survival and prevention of limb amputation, were achieved when compared with conservative medical therapy. In addition, more than half of the patients receiving PPI were later re-hospitalized. It should be noted that about two-thirds of patients from the PPI group who were re-hospitalized were found to have restenosis. Thus, it is assumed that frequent restenosis after PPI contributed to the increased incidence of re-hospitalization. Although one could argue that more advanced atherosclerosis of the SFA lesions contributed to the more frequent incidence of re-hospitalization in the PPI group, this assumption cannot be supported since patients in the PPI group had less severe lesions than the control group at baseline.

Prospective studies comparing the long-term outcome of PPI compared with medical therapy are limited![17] Perkins and colleagues reported that despite significant initial improvement in ABI after PPI, there was no significant difference in patients' walking distance between those who had undergone PPI compared with exercise therapy after 70 months of follow-up![20] Whyman et al also examined the outcome of PPI in patients treated with low-dose aspirin, exercise training, and smoking cessation![21] After 2 years of follow-up, neither walking distance nor ABI were significantly different between patients who had or had not undergone PPI. It must be noted that these studies included patients with suprainguinal as well as infrainguinal lesions, and were not intended to determine the outcome of PPI for SFA lesions. Considering the fact that PPI for suprainguinal lesions is generally associated with a lower restenosis rate than that for infrainguinal lesions, it appears that PPI for SFA lesions does not achieve a better outcome compared with medical treatment. The current study underscores this assumption by showing that, despite a favorable short-term outcome, PPI does not provide superior long-term benefits compared with conservative medical therapy in patients with SFA occlusive disease, and suggests that medical therapy may continue to remain the primary treatment strategy for this group of patients.

The use of stents in SFA has not been shown to be more beneficial than plain old balloon angioplasty![16,22–24] Thus, the TASC recommends the use of stents only for short SFA lesions and advise that they be used only in bail-out situations. In the present study, based on this recommendation, stents were used only for bail-out situations, and the long-term outcome was comparable to that of the balloon angioplasty. Schillinger et al recently reported that the use of self-expandable nitinol stents for SFA lesions yielded results that were superior to those of balloon angioplasty! The rate of restenosis on angiography was 24% in the stent group and 43% in the balloon angioplasty group, and at the 1-year follow-up, the rate on duplex ultrasonography was 37% and 63%, respectively. The advantages of nitinol stents include improved radial force, the ability to recover their shape after being crushed, and reduced foreshortening, which allows precise placement. Whether the use of newer-generation stents ultimately leads to better long-term outcomes beyond that presently offered by medical treatment awaits further investigation.

Conclusions

The current study demonstrates that despite a favorable short-term outcome, PPI does not provide superior long-term benefits compared with conservative medical therapy in patients with SFA occlusive disease, suggesting that medical therapy will continue to remain the primary treatment strategy for this group of patients.

Acknowledgments

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