The results of in situ saphenous vein bypass for infrainguinal arterial reconstruction: Comparison between two types of valvulotomes

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PURPOSE: To evaluate the authors' experiences with in situ saphenous vein bypasses that were performed using two types of valvulotomes and to respectively compare their efficacy on the basis of the operative outcomes.

METHODS: Between June 1993 and December 2008, 103 constructive in situ saphenous vein bypasses were performed, of which 53 were performed between 1993 and 2000 using an Insitucat valvulotome (B Braun Melsungen AG, Germany), and 50 were performed between 2000 and 2008 using a LeMaitre valvulotome (LeMaitre Vascular Inc, USA).

RESULTS: There were no statistical differences with regard to age, sex and bypass procedures between the two groups. Critical limb ischemia

($P=0.021$) and diabetes ($P=0.005$) were more frequent in the LeMaitre group than the Insitucat group. Intraoperative graft revisions ($P=0.079$) and graft spasms ($P=0.638$) were less frequent in the LeMaitre group. Graft failures in the perioperative period or within the first year were less frequent in the LeMaitre group. The five-year cumulative primary patency rates were 63.2% and 59.8% in the LeMaitre and Insitucat groups, respectively ($\chi^2=0.390$, not significant). The five-year cumulative secondary patency rates were 91.9% and 81.7% in the LeMaitre and Insitucat groups, respectively ($\chi^2=2.690$, not significant).

CONCLUSIONS: The results suggested that there were no significant differences in the outcome and adverse effects between the two types of valvulotomes for in situ saphenous vein bypass.

Key Words: *In situ saphenous vein bypass; Infrainguinal arterial occlusive disease; Patency rate; Valvulotome; Vein graft*

The in situ saphenous vein bypass technique has been widely used in clinical practice for infrainguinal arterial reconstruction because of the following advantages it offers: superiority of autogenous reconstructions, the possibility of using the ipsilateral saphenous vein, and accessibility for post-operative graft surveillance and revision. For an in situ vein bypass, a safe and precise procedure for valve destruction is required, and different types of valvulotomes have been developed for obtaining optimal results after valvulotomy.

Both Insitucat (B Braun Melsungen AG, Germany) and LeMaitre (LeMaitre Vascular Inc, USA) are retrograde valvulotomes; in Japan, the former has been available since 1993 and the latter since 2000. The purpose of the present study was to evaluate our experience with in situ saphenous vein bypass procedures using the two valvulotomes and to retrospectively compare their efficacy on the basis of the operative outcomes.

METHODS

Between June 1993 and December 2008, 103 constructive in situ saphenous vein bypasses were performed at the Nayoro City General Hospital (Hokkaido, Japan). Two different valvulotomes were used for vein valve destructions. The Insitucat valvulotome was used in 53 in situ bypasses conducted between 1993 and 2000, and the LeMaitre valvulotome was used in 50 in situ bypasses conducted between 2000 and 2008.

In situ saphenous vein bypass was performed as follows: the saphenous vein, and the inflow and outflow arteries were exposed at the anastomotic site. The saphenous vein was divided at the saphenofemoral junction, and the most proximal valve was incised or cut under direct vision. Proximal

anastomosis was completed and declamped. Next, the vein graft was exposed to arterial pressure. A valvulotome was inserted from the distal end of the vein graft to just below the proximal anastomosis, and pulled through at least twice. After a good pulse and adequate flow through the graft was confirmed, a distal anastomosis was constructed and blood flow was reperused. After the location of the arteriovenous fistula was defined by angiography, they were ligated and divided. Finally, a completion angiography and Doppler flow measurement were performed for detecting abnormalities of the graft and anastomotic site.

The results of the in situ saphenous vein bypass were analyzed and compared between the two valvulotomes.

Statistical analysis

Results were expressed as mean $\pm$ SD. Statistical differences between the two groups were compared using an unpaired Student's *t* test for the means or using a χ^2 test for the variables. $P \leq 0.05$ was considered to be statistically significant. The cumulative patency curve was analyzed by log-rank test.

RESULTS

Patient characteristics of the two groups are presented in Table 1. There were no statistical differences between the two groups with regard to age, sex and bypass procedures. Critical limb ischemia ($P=0.021$) and diabetes ($P=0.005$) were more common in the LeMaitre group.

Intraoperative graft revisions because of incorrect valve incision, graft injury or thrombosis at the valve site were less common in the LeMaitre group ($P=0.079$). Graft spasms were

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TABLE 1
Patient characteristics

	Insitucat* group (n=53)	LeMaitre† group (n=50)	P
Age, years, range (mean ± SD)	49–82 (70.3±6.5)	52–84 (70.7±6.9)	0.719
Male/female sex, n/n	49/4	40/10	0.120
Fontaine score, n (%)			
2	33 (62.2)	18 (36.0)	0.021
3	11 (20.9)	14 (28.0)	
4	9 (16.9)	18 (36.0)	
Diabetes, n (%)	17 (32.1)	30 (60.0)	0.005
Bypass type, n (%)			
FPBK	28 (52.8)	25 (50.0)	0.774
FC	25 (47.2)	25 (50.0)	

*B Braun Melsungen AG, Germany; †LeMaitre Vascular Inc, USA. FC Femorocrural bypass; FFBK Femoropopliteal below-knee bypass

TABLE 2
Adverse effects and events

	Insitucat* group (n=53)	LeMaitre† group (n=50)	P
Intraoperation			
Revision	7 (13.2)	1 (2.0)	0.079
Spasm	3 (5.7)	1 (2.0)	0.638
Perioperation			
Failure	2 (4.0)	1 (2.0)	0.959
Within first year			
Stenosis	6 (11.3)	2 (4.0)	0.308
Unknown	5 (9.4)	1 (2.0)	0.234

Data presented as n (%). *B Braun Melsungen AG, Germany; †LeMaitre Vascular Inc, USA

also less common in the LeMaitre group ($P=0.638$). Graft failures in the perioperative period were observed in two patients in the Insitucat group and one patient in the LeMaitre group. Graft failures due to partial stenosis, except for anastomotic lesions and host disease progressions within the first year after bypass were also less common in the LeMaitre group. Although problems associated with the graft appeared to be less common in the LeMaitre group, the adverse effects were similar between the two groups (Table 2).

The five-year cumulative primary patency rate was 63.2% in the LeMaitre group and 59.8% in the Insitucat group ($\chi^2=0.390$) (Figure 1). The five-year cumulative secondary patency rate was 91.9% in the LeMaitre group and 81.7% in the Insitucat group ($\chi^2=2.690$) (Figure 2). None of the rates were statistically significant. The patency rates of both groups improved after partial revisions of the stenotic graft lesions.

DISCUSSION

The long-term patency rate of infrainguinal arterial bypass is thought to be affected by the inflow artery, the outflow artery and the bypass conduit. An autogenous vein graft is the most valuable conduit for infrainguinal arterial reconstruction, and the quality of the vein mostly affects the patency rate (1).

In situ saphenous vein bypass was first introduced by Rob et al (2) and Hall (3). This technique has been widely used because of several benefits it offers. First, it minimizes endothelial injury by preserving the vasa vasorum, thereby

Figure 1) The primary patency rate. Insitucat, B Braun Melsungen AG, Germany; LeMaitre, LeMaitre Vascular Inc, USA. CPR Cumulative patency rate

Figure 2) The secondary patency rate. Insitucat, B Braun Melsungen AG, Germany; LeMaitre, LeMaitre Vascular Inc, USA. CPR Cumulative patency rate

theoretically improving graft patency (4). Second, because of the smaller incisions required, the technique avoids or minimizes skin complications. Third, because of the natural taper of the in situ vein, the larger diameter of the vein can be anastomosed to the larger proximal artery, and the smallest diameter of the vein can be anastomosed to the smaller outflow artery. Better outcomes with in situ saphenous vein bypass have been reported with the development of instruments and an increase in the experience of the vascular surgeons (5-9).

Thus far, several instruments for performing in situ bypass have been introduced; these instruments have varying features. It is essential to develop a safe and precise procedure to enable valve destruction. Batson and Sottirai (10) indicated that early graft failures occurred mainly because of thrombosis at the valve site due to incomplete valvulotomy or intimal laceration during the in situ saphenous vein bypass. Moreover, intimal trauma influences the late development of stenotic lesions at the valvulotomy site. Alback et al (11) also reported that incomplete valvulotomy or intimal laceration was caused by a size mismatch between the diameter of the vein and the cutting head of a valvulotome.

We have performed in situ saphenous vein bypasses for infrainguinal arterial reconstructions using Insitucat valvulotomes since 1993 and using LeMaitre valvulotomes since 2000. Both instruments are retrograde valvulotomes, but each has some advantages and disadvantages. The cutting head of the LeMaitre valvulotome is self-sizing and self-centring (12,13). This allows effective and safe valve destruction, and ensures the prevention of mismatch between the diameter of

the vein and the cutting head of the valvulotome. On the other hand, the Insitucat valvulotome is a simple instrument and easy to handle because of its fixed cutting head. However, the fixed cutting head has a disadvantage: distal graft spasm is possibly introduced while withdrawing the valvulotome through the distal end of the vein – which is most likely to be the smallest in diameter – because of the mismatch in calibre size. In addition, adjusting the size of the cutting head according to the distal portion of the vein results in incomplete valve destruction in the proximal parts of the graft. Alback et al (11) and Malmstedt et al (14) reported that the majority of incompletely destroyed valves were found in the proximal parts of the graft, resulting from a size mismatch between the diameter of the vein and that of the valvulotome.

In our series, although the primary and secondary cumulative patency rates were similar between the two groups, the rates in the LeMaitre group were higher than those in the Insitucat group. Intraoperative modification of the vein graft is known to be associated with a significant increase in the incidence of late-appearing bypass stenosis, and the occurrence and progression of fibrointimal hyperplasia has been reported to be associated with bypass modification (7). The primary patency rate is influenced by initial technical error and vein quality. Therefore, an effective instrument for valve destruction is necessary to avoid early graft obstruction and to obtain good patency after in situ bypass. Secondary cumulative patency rate can be maintained by compulsive bypass surveillance and elective revision of the failing bypass graft (15,16). In situ vein

bypass grafts facilitate postoperative graft surveillance and graft revision. Our results indicate a high secondary patency rate and the importance of graft surveillance.

Limitations

There are several limitations to our study. First, our investigation was retrospective. Second, the sample size was relatively small. Third, the patients who underwent bypass with an Insitucat valvulotome were from an older series, whereas those who underwent bypass with a LeMaitre valvulotome were from a recent series; this led to a historical difference. There was a possibility that the surgeon experienced a learning curve when performing the in situ vein bypass technique. The experience of the surgeon might be one of the determinant factors affecting the results of in situ saphenous vein bypass (7).

SUMMARY

The effectiveness of the LeMaitre valvulotome, which has a self-sizing and self-centring cutting head, for performing in situ saphenous vein bypass might be higher than that of the Insitucat valvulotome. However, there were no statistically significant differences between them. The proper skill and knowledge of valvulotome characteristics seemed to be necessary for in situ saphenous vein bypass.

CONFLICT OF INTEREST: The authors do not have any financial or other types of interest in the manufacturers or distributors of the valvulotomes.

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