Chapter 6: Transit-time volume flow measurements in autogenous femoro-distal bypass surgery for intra-operative quality control

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Abstract

Objective: The aim of this study was to assess intraoperative transit-time volume flow measurements (VFM) as a tool for intraoperative evaluation of lower extremity arterial bypass grafts and to predict their patency.

Methods: We analyzed 273 consecutive patients who had an infrainguinal bypass procedure using greater saphenous vein from 1998 until 2008. 103 had an intraoperative VFM. All intraoperative revisions were recorded and analyzed. Patency and revision rate were compared between those receiving and not receiving intraoperative VFM. Cox regression was used for analysis of predictors of patency.

Results: Primary patency at 1 and 2 years was 75 and 67%, respectively, in patients receiving intraoperative VFM versus 72 and 69 % in those without VFM (P=0.79). In the VFM-group, 12% had an immediate revision versus 6% without VFM (P=0.06). In the VFM-group, 4% underwent revision to salvage the bypass within the first postoperative 30 days versus 6% without VFM (P=0.32). Patency was not associated with use of VFM. ROC- curve was significant for occlusion at 30 days postoperatively, but with a low predictive value (P=0.019, area under the curve; 0.648)

Conclusions: VFM may be helpful in selecting bypasses requiring immediate revision to prevent postoperative occlusion. The use of VFM is not significantly associated with patency.
Introduction

Infrainguinal arterial bypass operations are routinely performed in patients with severe lower limb ischemia. Autogenous vein is the preferred conduit, particularly for bypasses extending below the knee. [1] Autogenous femorodistal bypass patency within 30 days postoperatively varies between 70 and 95%. [2-6] Known causes of bypass occlusion are proximal disease causing suboptimal inflow, poor outflow tract quality and intrinsic graft related factors. [7-10] Some predictions on bypass patency can be made using the SVS/ISCVS system, although contradicting results on the reliability of this tool have been reported. [11-18] Various methods of intra-operative bypass quality assessment are at the surgeon’s disposal, of which angiography is the reference standard. Angiography, however, is relatively time-consuming. This is the main reason that surgeons have been searching for other reliable, but more user-friendly methods of intra-operative functional evaluation of vascular reconstructions to determine whether direct revision is necessary. The purpose of this study was to evaluate the usefulness of transit-time volume flowmetry (VFM) for intra-operative assessment of bypass function and its ability to detect abnormal flow as an indication for short term failure and occlusion due to technical errors, and to select bypasses that require immediate revision. Secondarily, we determined the value of VFM as a predictor of 30-day, 3 and 6 month patency.

Patients and methods

Between 1999 and 2008, a total of 273 consecutive patients underwent infra-inguinal bypass surgery with reversed greater saphenous vein (GSV) grafts for claudication (Fontaine 2, n=61), ischemic rest pain (Fontaine 3, n=92), gangrene (Fontaine 4, n= 120), of which 103 had intraoperative VFM. All subjects were analyzed pre-operatively with non-invasive vascular
laboratory tests (ankle/brachial pressure index and treadmill provocation) and digital subtraction angiography (DSA) or contrast enhanced magnetic resonance angiography (ce-MRA). Recipient arteries were the supra- or infragenual popliteal artery, the perineotibial trunk, crural or pedal vessels. (Figure 1)

Patients were operated under general anesthesia. An intraoperative VFM was performed in 103 patients (64% male, mean age 67), using the Transonic® Flowmeter, Model HT107 (Transonic Systems Inc., Ithaca, NY, U.S.A.). This ultrasonic transit-time flow meter measures volume flow within the vein graft, for which a precalibrated probe is placed around the conduit. Probes used were the 3 millimetre (for 2.4-4.0 millimetre GSV diameters), 4 millimetre (3.2-5.0 millimetre GSV diameters) and 6 millimetre (4.5-7.5 millimetre GSV diameters, HQD/FSB-series, without handle, L-reflector with slide). The probe was always placed on the conduit proximally, just distally to the proximal anastomosis. All bypasses were reversed GSV conduits, so there were no undetected persistent vein branches interfering with the measurements. No vasodilative drugs were administered before flow measurements. Patient selection for VFM was exclusively based on the surgeon’s preference. One of the surgeons applied VFM routinely, provided that a probe was available. Two other surgeons only sporadically applied VFM. A flow of less than 60 milliliter/minute (ml/min) was considered an indication for revision (thrombectomy or anastomotic revision) or additional intraoperative imaging. In more distally inserted grafts (crural, pedal), a (arbitrary) flow of 40 ml/min was accepted. [18] In those cases in which VFM was not applied the bypass was assessed by pulse palpation and/or Doppler. Completion angiography or duplex ultrasonography was not routinely performed. All patients were prescribed coumadin post-operatively, unless there was a compelling contraindication. In such cases aspirin was prescribed.

After discharge, patients had periodical physical examinations and duplex ultrasonography at 6 weeks and 6 and 12 months in order to assess bypass
integrity and to detect graft occlusion or stenosis. Revision was done in case of a peak systolic velocity ratio larger than 4.

General characteristics were retrieved via chart review. (Table 1) Patient demographics, operation type, flow measurements and other variables were recorded and analyzed using Statistical Package for Social Sciences version 16.1 SPSS® (SPSS, Chicago, Illinois, USA). Dichotomous variables were tested with the Chi-square test and continuous variables with the Student’s t-test. Analysis of variance was conducted for the comparison of more than 2 groups. Variables that were selected for multivariate analysis were age, sex, symptomatic coronary disease, smoking, the use of oral anticoagulants or aspirin, the presence of hypertension, diabetes, hypercholesterolaemia, ASA-classification, ankle/brachial pressure index, previous bypass surgery in the affected limb, previous percutaneous transluminal angioplasty, operation time, bypass type, first intraoperative flow, flow after immediate revision, postoperative hemorrhagic complications, a second operation for any reason other than bypass revision or thrombectomy, and wound infection. These variables were all entered in a Cox regression model after which variables were left out one by one (backward method), beginning with the least significant one. When the omission of a variable resulted in a -2 Log likelihood change greater than 3.84, the variable was considered indispensable, and put back, eventually leading to the most fit model. The primary outcome was defined as graft occlusion or re-intervention to prevent occlusion. Patency of bypasses with and without intraoperative VFM was compared with a log-rank test (Kaplan-Meier). Receiver operating characteristic (ROC) curves were calculated to establish a threshold value for VFM predicting 30-day, 3 and 6 month patency.
Table 1. Patient characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=273)</th>
<th>VFM (n=103)</th>
<th>No VFM (n=170)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>173 (64%)</td>
<td>70</td>
<td>103</td>
<td>0.2</td>
</tr>
<tr>
<td>Mean age (SD) [years]</td>
<td>67 (±13)</td>
<td>66</td>
<td>68</td>
<td>0.16</td>
</tr>
<tr>
<td>Smoking</td>
<td>203 (74%)</td>
<td>81</td>
<td>122</td>
<td>0.44</td>
</tr>
<tr>
<td>Symptomatic coronary disease</td>
<td>89 (33%)</td>
<td>35</td>
<td>54</td>
<td>0.69</td>
</tr>
<tr>
<td>Hypertension</td>
<td>152 (56%)</td>
<td>56</td>
<td>96</td>
<td>0.71</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>96 (35%)</td>
<td>40</td>
<td>56</td>
<td>0.94</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>119 (44%)</td>
<td>51</td>
<td>68</td>
<td>0.14</td>
</tr>
<tr>
<td>Fontaine classification type II</td>
<td>61 (22%)</td>
<td>26</td>
<td>35</td>
<td>0.41</td>
</tr>
<tr>
<td>type III</td>
<td>93 (34%)</td>
<td>38</td>
<td>55</td>
<td>0.61</td>
</tr>
<tr>
<td>type IV</td>
<td>120 (44%)</td>
<td>41</td>
<td>79</td>
<td>0.24</td>
</tr>
</tbody>
</table>

**Results**

Of all patients receiving intraoperative VFM, 12% (n=12) had immediate intraoperative revision because of suspected bypass malfunction (VFM <60ml/min (popliteal) or VFM<40 ml/min (crural/pedal), details; see table 2), versus 6% (n=9) in the patient group not receiving intraoperative VFM (P=0.06). The mean volume flow before and after intraoperative intervention was 24 and 68 ml/min (mean difference 44 ml/min, 95% confidence interval 18-70, P=0.003). Reintervention within 30 days took place in 4 (4%) patients from the flowmetry group, and in 10 (6%) of the patients that did not have VFM (P=0.32). Mean volume flow at the end of surgery was 134 ml/min. Mean VFM values of bypasses failing and not failing within 30 days were 99 ± 66 and 147 ± 94 ml/min, respectively (P=0.01). Crural and pedal bypasses had a significant lower flow volume (P=0.001, see figure 1).

The mean follow up was 23 months (range 1-114). Primary patency after 1 and 2 years was 74 and 68%, respectively. As Kaplan-Meier curves in figure
2 show, no difference in patency was found between patients who did and patients who did not have an intraoperative flow measurement and prompt revision when indicated (P=0.79).

<table>
<thead>
<tr>
<th>Patient</th>
<th>Bypass type</th>
<th>VFM 1</th>
<th>VFM 2</th>
<th>Intervention</th>
<th>Problem</th>
<th>Primary patency</th>
<th>Late outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>M, 79 y</td>
<td>FC</td>
<td>42</td>
<td>62</td>
<td>TC</td>
<td>?</td>
<td>1</td>
<td>BKA after 1 month</td>
</tr>
<tr>
<td>M, 66 y</td>
<td>FC</td>
<td>0</td>
<td>0</td>
<td>TC</td>
<td>PO</td>
<td>3</td>
<td>BKA after 3 months</td>
</tr>
<tr>
<td>M, 87 y</td>
<td>FC</td>
<td>30</td>
<td>30</td>
<td>TC</td>
<td>PO</td>
<td>1</td>
<td>BKA after 1 month</td>
</tr>
<tr>
<td>F, 78 y</td>
<td>IFP</td>
<td>5</td>
<td>12</td>
<td>TC</td>
<td>PO</td>
<td>0</td>
<td>New bypass after 15 months</td>
</tr>
<tr>
<td>M, 69 y</td>
<td>SFP</td>
<td>20</td>
<td>80</td>
<td>TC</td>
<td>Thrombus in popliteal artery</td>
<td>19</td>
<td>RC</td>
</tr>
<tr>
<td>F, 58 y</td>
<td>SFP</td>
<td>50</td>
<td>75</td>
<td>TC</td>
<td>?</td>
<td>5</td>
<td>RC</td>
</tr>
<tr>
<td>M, 54 y</td>
<td>FC</td>
<td>15</td>
<td>100</td>
<td>Shortened</td>
<td>Kinking</td>
<td>6</td>
<td>RC</td>
</tr>
<tr>
<td>M, 70 y</td>
<td>SFP</td>
<td>13</td>
<td>80</td>
<td>Shortened</td>
<td>Thrombus in popliteal artery</td>
<td>open</td>
<td></td>
</tr>
<tr>
<td>M, 64 y</td>
<td>SFP</td>
<td>60</td>
<td>180</td>
<td>Lysis</td>
<td>Stricture</td>
<td>open</td>
<td></td>
</tr>
<tr>
<td>M, 55 y</td>
<td>SFP</td>
<td>30</td>
<td>60</td>
<td>?</td>
<td>open</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M, 76 y</td>
<td>PP</td>
<td>20</td>
<td>115</td>
<td>patch</td>
<td>Stenosis in conduit</td>
<td>5</td>
<td>D</td>
</tr>
<tr>
<td>M, 73 y</td>
<td>PP</td>
<td>5</td>
<td>20</td>
<td>TC</td>
<td>PO + ?</td>
<td>0</td>
<td>BKA after 1 week.</td>
</tr>
</tbody>
</table>

Figure 1. Distribution of bypass types (left column, total) and their flow (right column, mean in ml/min, ±SD). SgFp: supragenicular femoropopliteal; IgFp: infragenicular femoropopliteal; FC: femorocrural; DFp: distal femoropopliteal (from the distal SFA to the infragenicular popliteal artery); FP: femoropedal; PP: popliteopedal.
Cox regression analysis resulted in a stable model of ten potential predicting factors, of which “operation time” (P=0.03), “postoperative bleeding” (P=0.05) and “reoperation” (P<0.001, any type of reoperation other than bypass revision surgery) were significantly associated with decreased primary patency. The variable “flow volume measurement” was not significantly related (P=0.29); patients that had intraoperative quality control with VFM did not have a better patency than those without VFM. Patients having prompt revision after intraoperative VFM had a poor primary patency. In 8 (66%) of them, bypass failure occurred within 6 months. (Table 3)
To define a threshold value for identification of bypasses at risk, ROC-curves for VFM as a predictor of bypass failure at 30 days and 3 and 6 months were calculated for all bypass types, showing an insignificant, linear relationship between sensitivity and 1 minus specificity at 3 and 6 months. At 30 days, the ROC-curve was significantly associated with occlusion (P=0.019). The predictive value was low (area under the curve; 0.648). (Figure 3)
Discussion

In this study we found no convincing evidence that VFM has additional value in predicting bypass failure. No statistically significant difference in patency was noted between groups receiving and not receiving intraoperative volume flow measurements. The difference we found in direct revision rates between patients that had VFM and those who had not suggests that VFM may be helpful in intraoperative graft control, however, this difference was not significant (P=0.06). Patients with and without intraoperative VFM had a 30-day revision rate of 4 and 10%, respectively (P=0.29). Intraoperative VFM and subsequent prompt revision does not necessarily result in better patency, because VFM cannot differentiate between bypasses that can be salvaged successfully and those
that would have failed anyway (e.g., due to poor outflow). Owing to the small number of patients included in this study it is impossible to draw any firm conclusions on the significance of the differences demonstrated.

ROC-curves at 3 and 6 months were not significant. At 30 days, the ROC-curve was significant, but its predictive value was limited. On one hand, a larger flow volume chosen as a threshold value would result in many false positives leading to a disproportionate number of intraoperative revisions, where, on the other hand, a lower threshold flow volume would lead to underestimation and inadequate detection of bypasses that need immediate revision. Therefore, it was not possible to identify a meaningful threshold flow volume that can serve as a basis for intraoperative decision making. So, although the diagnostic accuracy of VFM to predict 30-day patency and identify bypasses that require immediate revision is limited, it may nevertheless indicate bypasses at risk. In addition to the option of prompt revision, these bypasses may also benefit from intensified follow up, e.g. by means of earlier and more frequent duplex ultrasonography.

The goal of intraoperative bypass testing is to select technically inadequate bypasses that require immediate revision to prevent failure later. In their efforts to judge graft sufficiency and optimize patency during infra-inguinal bypass surgery, surgeons often make their intra-operative decisions based on experience, for example, using pulse palpation. Their judgment is led by criteria that sometimes lack definition and are difficult to quantify, such as graft diameter, anastomosis width and outflow tract sufficiency. Alternatively, surgeons judge their bypasses with the intraoperative use of instruments such as duplex ultrasonography, VFM, continuous wave Doppler (CWD) ultrasonography and, less frequently, angioscopy. [19-22] Many reports have been published on different methods of intra-operative bypass quality control. However no randomised controlled studies have been published. Some advocate CWD ultrasonography and ultrasonic volume flowmetry as a viable tool for intra-operative functional bypass testing, but others reject these methods. [11] In contrast with VFM, investigators found CWD ultrasonography to be a highly effective tool for
intraoperative detection of technical inadequacies (with a likelihood ratio of 14.7 versus 1.3 for VFM). [23] However, others compared CWD ultrasonography with postoperative duplex ultrasonography at 1 week and found that 35% of the bypasses that were deemed adequate intraoperatively, were regarded as at risk at follow up duplex ultrasonography, one week after surgery, thus dismissing CWD ultrasonography as an intraoperative tool for quality control. [24] Also, intraoperative bypass duplex scanning has been proposed as a routine intraoperative control modality. A peak systolic velocity ratio of ≥ 3 is strongly associated with early bypass failure (likelihood ratio: 6.8). Others found VFM to be a reliable predictor of 1-year graft patency in femoro-crural reconstructions and graft occlusion after infrainguinal bypass surgery. In a retrospective series of 257 infrainguinal bypasses, those findings were confirmed. [18,25-27] However, the role of VFM in intraoperative graft assessment is disputed. [11]

The limitations of this study include the retrospective nature and the relatively small number of patients included. However, the most important weakness is the process of selection of bypasses that were subjected to VFM. In particular, the sporadic use of VFM by two of the three surgeons may have introduced a considerable risk of selection bias. The influence of selective VFM in bypasses that are suspected to be at risk is likely to increase the number of prompt revisions. However, the effect on the 30-day revision rate and patency is unclear, because prompt revision is no guarantee for a better outcome as we have seen in our group of patients. This may be explained by the fact that the actual cause of a poor VFM result is not always clear, or cannot be resolved (e.g., poor outflow). VFM in general was used randomly and exclusively at the surgeon’s preference, provided that the flow meter was available. Also, the calculated odds ratio for postoperative bleeding suggests that the occurrence of this complication diminishes the chances of bypass failure. In multivariate analysis, both “reoperation” and “postoperative bleeding” were in the most fit statistical model. However, these two variables are closely related,
because postoperative bleeding was always followed by reoperation. The close relationship between these variables represents a disturbing factor, providing an explanation for the highly unlikely “protective” effect of postoperative bleeding demonstrated in the results.

From these data, we conclude that, in contrast with previous reports, intraoperative use of VFM is not associated with a better primary patency. Intraoperative VFM may help to identify bypasses that need immediate revision. VFM does not appear to reduce the 30-day post-operative revision rate in our population. However, the 30-day ROC-curve was significant; therefore VFM cannot be disqualified as an intraoperative quality control tool based on this small study. Previously reported threshold flow volumes may be applicable for intraoperative bypass assessment. The question whether intraoperative identification of a bypass at risk with VFM should be followed by prompt revision or by intensified postoperative surveillance depends on the threshold value used and cannot be answered from our data.
References