

ANNEXES TO CHAPTER 5

**Clinical Question XV. Is there a treatment with better outcomes (percutaneous transluminal angioplasty versus surgery) in juxta-anastomotic stenosis, assessed in terms of patency and/or thrombosis and cost/benefit?**

<b>Patients with synthetic graft and juxta-anastomotic stenosis in the vascular access</b>	
<p>Only one randomised clinical trial (RCT) was identified comparing surgery and angioplasty in patients with synthetic graft and juxta-anastomotic stenosis (Brooks 1987). Apart from this study, no other publications were found in which surgery is directly compared with angioplasty.</p>	
<p>The Brooks RCT (1987) included 43 patients with stenosis of vascular access involving bovine or synthetic graft in the forearm, 19 of whom were randomised to surgery and 24 to percutaneous angioplasty. Mean access patency duration was longer for the surgery group, at 12 months, compared to only 4 months for the angioplasty group. This difference was statistically significant (<math>p &lt; 0.01</math>). In addition, the average cost of the surgical repair was slightly less than angioplasty, \$2100 vs \$2400. They concluded that to achieve long-term access patency, surgical treatment is the method of choice, although in special circumstances angioplasty might have a role.</p>	<p><b>Moderate quality</b></p>
<b>Patients with arteriovenous fistula and juxta-anastomotic stenosis</b>	
<p>No clinical trials have been identified that compare angioplasty and surgery for the treatment of stenosed vascular access in patients with fistula. Two publications were found that compared series of patients treated with surgery and patients treated with angioplasty.</p>	
<p>In the Napoli study (2010), 66 percutaneous angioplasties and 68 surgical interventions were performed on 43 and 57 patients respectively, all uraemic with juxta-anastomotic stenosis of the fistula. They evaluated the efficacy of the interventions by measuring the brachial artery flow by colour Doppler ultrasound. Angioplasty was performed on 50 patients, but failed in seven and they went on to have surgery. In the 43 patients in whom angioplasty worked, there was a mean increase of <math>99 \pm 70\%</math> (<math>p &lt; 0.001</math>) in blood flow. Restenosis occurred in 17 patients; two were treated by surgery and 15 by angioplasty. Restenosis occurred again in six of these 15 patients; after the second restenosis, five of the six patients had angioplasty with stenting and one underwent surgery. Access failure occurred in three patients within the following 12-17 months. New fistulae (upstream) were created in the 57 patients treated by surgery and they worked well, with a mean increase of <math>102 \pm 71\%</math> in the blood flow (<math>p &lt; 0.001</math>). Restenosis occurred in 15 patients; nine were treated by surgery and six by angioplasty. Access failure occurred in nine patients within the following 3-36 months.</p> <p>Comparative analysis between these two options, performed using the Kaplan-Meier method, showed better primary patency for surgery (<math>p &lt; 0.05</math>), but with no differences in assisted primary patency. The authors concluded that surgery showed better primary patency than angioplasty and that there was a higher tendency towards restenosis with angioplasty. However, since failed angioplasty can be subsequently corrected by surgery, and both techniques have similar assisted patency, they suggest performing angioplasty first, reserving surgery for cases in which it fails.</p>	<p><b>Low quality</b></p>

## Spanish Clinical Guidelines on Vascular Access for Haemodialysis

<p>The study by Tessitore (2006) performed a retrospective analysis of clinical data from 64 patients with juxta-anastomotic stenosis (&gt;50%) of the fistula in the lower part of the forearm, 43 of whom were treated by percutaneous angioplasty and 21 by surgery (11 with proximal neo-anastomosis and 10 with polytetrafluoroethylene graft). The initial success of the procedure was 100% for surgery and 95% for the percutaneous angioplasty (p=0.539; difference not statistically significant).</p> <p>The restenosis rate was 0.168 and 0.519 events per fistula-year for surgery and angioplasty respectively (p=0.009). The type of procedure was the only variable to be significantly associated with restenosis, with an adjusted relative risk 2.77 times higher (95% CI: 1.7 to 7.17, p=0.036, difference statistically significant) for angioplasty than for surgery. The procedure failure rate was 0.110 and 0.097 events per fistula-year for surgery and angioplasty respectively (p=0.736; difference not statistically significant). The cost profile was similar for the two procedures.</p> <p>The authors considered that despite the higher rate of restenosis for angioplasty, as the two procedures show similar primary assisted patency and costs, if performed with close monitoring for restenosis, they should be considered as equally valid alternatives for complementing preventive treatment for stenosis of the anastomosis in forearm fistulae.</p>	<p><b>Low quality</b></p>
<p><b>Summary of evidence</b></p>	
<p>There is no conclusive evidence on mature fistulas with stenosis. The available data come from comparisons of clinical series, with non-homogeneous results. The clinical series found that surgery provides better outcomes than angioplasty.</p>	<p><b>Low quality</b></p>
<p><i>For synthetic grafts</i>, the evidence comes from a randomised clinical trial, which showed that surgery was significantly better than angioplasty for achieving longer duration of patency for the vascular access.</p>	<p><b>Moderate quality</b></p>
<p><b>Patients' values and preferences</b>  <i>No relevant studies related to this aspect have been identified.</i></p>	
<p><b>Use of resources and costs</b>  The Tessitore study (2006) estimated median costs of 1287 euros per graft-year (range 525 to 5438) for surgery and 876 euros (range 185 to 13824) for angioplasty.</p>	
<p><b>Recommendations [Proposal]</b></p>	
<p><b>Weak</b></p>	<p><i>For mature fistulae</i>, it is suggested that both surgery and angioplasty be assessed for the repair of juxta-anastomotic stenosis in the vascular access.</p>
<p><b>References</b></p>	
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**Table 1. STUDIES EXCLUDED**

<b>Study</b>	<b>Cause for exclusion</b>
Clark 2009	Does not compare surgery with angioplasty. Evaluates the angiographic changes following the use of a suturing device in haemodialysis access interventions.
Jimenez-Almonacid 2012	Does not compare surgery with angioplasty. All patients treated by surgery.
Lee (2013)	Interventions not on stenosed access, but on non-matured fistula.
Mickley 2003	Does not compare surgery with angioplasty.
Moncef 2010	Does not compare surgery with angioplasty. All patients treated by surgery.
Mortamais 2013	Does not compare surgery with angioplasty. Studies on long-term outcomes after endovascular treatments of fistula stenosis.
NCT00179192	In the USA Clinical Trials Register (ClinicalTrials.gov) we found a parallel, open-label, randomised clinical trial, at the Vanderbilt University Medical Center, Nashville, Tennessee, led by Dr Ikizler (NCT00179192). This trial appears in the registry as terminated in October 2006. We contacted Dr Ikizler, who informed us that the study was not carried out due to lack of funding.
Ozkan 2013	Does not compare surgery with angioplasty. Study on the use of endovascular stenting in patients in whom angioplasty has not worked.
Turmel-Rodrigues 2010	Letter to the editor.