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GUIDELINES FOR THE ENDOVASCULAR TREATMENT OF PERIPHERAL VASCULAR DISEASE

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CLINICAL GUIDELINES

Guidelines for the Endovascular Treatment of Peripheral Vascular Disease

I C van Marle, M Veller, L Scholz, P Fourie, I Duncan, F Hellig, R Jardine

1. Introduction

Endovascular procedures have become an integral part of the treatment of peripheral vascular disease. Whereas some procedures have established their place alongside surgery, and are sometimes even preferable to surgery, others have barely moved from being experimental procedures to procedures under investigation. Endovascular procedures have been embraced with enthusiasm in South Africa and are being increasingly used by vascular surgeons, cardiologists and interventional radiologists. Although most of the procedures have been used for the correct indications, it has become apparent that some procedures are being over-utilised, used for the wrong indications and used without proper preoperative evaluation and postoperative follow-up. This impacts not only on the clinical results, but as most of these procedures are cost-intensive, it also has a definite impact on medical costs. It has therefore become apparent that clear guidelines and recommendations are needed.

The best scientific basis for any guideline or recommendation is level 1 evidence derived from prospective randomised trials. Very often this is not available, and recommendations have to be based on large retrospective series, prospective non-randomised studies and the collective experience of experts. In an effort to establish guidelines for South Africa a meeting of local experts was held in Pretoria in May 2003. During this Endovascular Consensus Meeting all aspects concerning the endovascular management of peripheral vascular disease were discussed intensively under the guidance of three international experts in this field: J Parodi (Buenos Aires, Argentina), D Vorwerk (Heidelberg, Germany), and L Inglese (Milan, Italy). These current guidelines are therefore based on the extensive discussions and lectures during this consensus meeting, as well as the latest publications and recommendations that had become available in the literature since then.

Guidelines are not absolute dictates but should provide a framework within which the reasonable physician can and should practise; it should take exceptional circumstances for a physician to practise outside this framework. These guidelines have also been presented to, and accepted by, the membership of the Vascular Society of Southern Africa and Interventional Radiology Society of South Africa.

Many new prospective trials are in progress, the results of which may eventually change current practice. These guidelines will therefore have to be revised regularly and it is envisaged that similar meetings will be held on a regular basis for this purpose.

We would like to acknowledge again the contributions made by the many experts during the consensus meeting in 2003. We would also like to thank the various companies whose generous financial support made the consensus meeting and the publication of these guidelines possible.

2. Abdominal aortic aneurysms (AAAs)

These guidelines are based on level 1 evidence as provided by 3 large prospective randomised trials (the UK Small Aneurysm Trial,[1] the ADAM Study,[2] the EVAR trial[3]), the Guidelines for the Management of Abdominal Aortic Aneurysms as accepted by the American Association for Vascular Surgery and the Society of Vascular Surgery,[4] as well as various recommendations from the EUROSTAR Study, a prospective multi-centre open audit (at this stage involving more than 4 200 patients).[1-4]

Based on the above, the following recommendations are made.

- The risk of rupture of small aneurysms (< 55 mm) is low (≤ 1% per annum). A policy of careful surveillance up to a diameter of 55 mm is safe, unless there is rapid expansion (> 1 cm per annum) or symptoms develop. Women appear to have a greater than average risk of rupture and elective repair may be indicated at 5 - 5.5 cm.[1,2,4,5]
- Many studies have demonstrated the equivalent early safety and efficacy of endovascular aneurysm repair (EVAR) compared with conventional open surgical repair, and there are many well-documented early benefits, including reduced peri-operative morbidity, fewer major adverse events, reduced hospital stay, fewer blood requirements and quicker recovery.[6,7] The EVAR trial 1 proved that in patients with large AAAs, treatment with EVAR reduced the 30-day operative mortality by two-thirds compared with open repair.[3]

Formulated by: **The Endovascular Consensus Meeting, Pretoria, 10/11 May 2003**

Societies Participating: **Radiological Society of South Africa (RSSA), South African Heart Association (SA Heart), Vascular Society of Southern Africa (VASSA)**

Editorial Committee: **C van Marle, M Veller, L Scholz, P Fourie, I Duncan, F Hellig, R Jardine**

- There is, however, concern about the long-term durability of EVAR. The cumulative rate of endoleak is almost 30% after 5 years, with up to 10% of patients requiring re-interventions per annum. Late conversions are required in 1 - 2% of patients per annum and there is an ongoing risk of rupture of 1% per annum, despite successful aneurysm occlusion.[8-10]
- In view of the uncertain long-term durability, long-term follow-up and surveillance are mandatory.
- EVAR is considered to be the preferred treatment for older and high-risk patients in whom open aneurysm repair poses an increased risk, as well as those with other clinical conditions, such as hostile abdominal conditions, likely to increase the risk of conventional repair.[4]
- High-risk (ASA III and IV) patients will benefit from endovascular aneurysm repair, provided that they do not die from the consequences of their co-morbid conditions within 1 year of the operation.[11]
- There is a significantly increased risk of adverse outcomes with endoleak, conversion to open repair and rupture if endovascular repair is used in patients with unsuitable anatomy.[4]
- At present there does not appear to be any justification for the view that endovascular repair of aneurysms should change the accepted size thresholds for intervention in most patients.[4]
- It is acknowledged that there are various prospective randomised trials in progress comparing endovascular with standard open repair, looking at various aneurysm sizes, as well as newer developments in stent graft technology that may change these recommendations in future.
- It is recommended that all endovascular aneurysm repairs in South Africa be done as part of the Vascular Society of Southern Africa (VASSA)/EVAR registry which is a local prospective open audit.

2.1 Guidelines for AAA repair

2.1.1 Aneurysm criteria

Degenerative (atherosclerotic) AAAs:

- fusiform aneurysms > 55 mm in maximum anteroposterior and transverse diameter
- tender non-inflammatory aneurysms irrespective of size
- saccular aneurysms > 2 x the diameter of the normal aorta
- where the aneurysm has increased in maximal diameter > 10 mm over a 12-month period using objective and validated forms of measurement.

2.1.2 Patient criteria

The above indications apply in patients who:

- are over 70 years of age
- are at high risk for standard open repair (ASA III and IV)
- have hostile abdominal conditions that would render standard open repair hazardous.

2.1.3 Aneurysm morphology requirements

Preoperative assessment of aneurysm morphology should be performed using spiral computed tomography (CT) with 3 mm cuts. Conventional arteriography is inadequate as the sole measurement for stent graft diameter sizing because it measures luminal diameter rather than true aneurysm diameter which should be from adventitia to adventitia.[12]

Infra-renal neck:

- Length > 10 - 15 mm
- Diameter ≤ 28 - 30 mm
- Angulation ≤ 60°
- No circumferential thrombus or calcification.

Iliac arteries:

- Maximum diameter ≤ 16 -18 mm
- Minimum diameter ≥ 7 mm
- Avoid heavily calcified or severely tortuous iliac arteries.

Caution should be exercised when occluding both internal iliac arteries.

Some stent grafts have bigger diameters and this should be taken into account when deciding on the ideal graft to fit aneurysm morphology.

2.1.4 Follow-up

Regular follow-up is required to detect endoleak, neck dilatation, enlargement of the aneurysm, etc.

- Duplex Doppler at 30 days, 3 and 6 months
- Spiral CT at 12 months and annually thereafter.

2.1.5 Caution

- At present there is no evidence supporting the endovascular treatment of small (< 5 cm) asymptomatic aneurysms.
- Open surgery is still the preferred treatment of choice in younger, fit and good-risk patients (ASA I and II) with a long life expectancy.

2.1.6. Skills required

Procedures should be performed by teams with adequate expertise in the open repair of AAAs (> 12 cases per annum) and percutaneous vascular interventions. It is therefore required that these teams consist of a vascular surgeon as primary operator or first assistant and an interventional radiologist or cardiologist.

Physicians wanting to start an endovascular programme should attend a training course at a centre with an established EVAR programme. Training should include: theory of aneurysm sizing and selection for EVAR, assisting with at least

5 cases, and performing at least 5 cases under supervision of an accredited proctor.

Official proctoring programmes are sponsored by various companies that manufacture stent grafts and are being monitored by VASSA.

2.2 Other indications for aortic stent grafting

2.2.1 Ruptured AAAs: endovascular treatment of ruptured AAAs promises to decrease the devastating morbidity and mortality of this condition.[13,14] This procedure should, however, only be performed in centres with a high volume of elective and emergency open aortic surgery and where there is extensive experience with the endovascular management of elective AAAs.

2.2.2 Thoracic degenerative aneurysms, acute and chronic type B dissections, intra-mural haematoma and penetrating ulcers: based on the limited evidence currently available, endovascular treatment appears to be as effective as open surgery, with decreased morbidity and mortality, and may therefore be the modality of choice for suitable patients. Existing indications for surgical intervention should be used.[15-17]

3. Peripheral arterial occlusive disease

Guidelines for the management of peripheral arterial occlusive disease (PAOD) were drawn up by the Trans Atlantic Inter-Society Consensus (TASC) Working Group and were published in 2000.[18] These guidelines are widely accepted internationally and form the basis for our own approach locally. It is strongly recommended that all physicians involved in the management of PAOD study this document closely. It was agreed that the committee accept the TASC guidelines in their entirety.

The TASC Working Group have defined 4 types of lesions based on lesion morphology. The 2 extremes are type A lesions in which the endovascular approach is the treatment of choice, and type D lesions in which surgery is the treatment of choice. Between these 2 groups are types B and C lesions in which no firm recommendations can be made about the preferred option. At present, endovascular treatment is more commonly used in type B lesions, and surgical treatment is more commonly used in type C lesions. It should, however, be emphasised that there is insufficient solid evidence to make any firm recommendations in the case of types B and C.

The indications for endovascular intervention for arterial occlusive disease are the same as for surgery, viz. lifestyle-limiting claudication and critical limb ischaemia. Patients should not be considered for endoluminal angioplasty or stenting in the absence of clear clinical indications.

3.1 Aorto-iliac disease (Table I)

Percutaneous transluminal angioplasty (PTA) is generally applied to more focal disease, for instance of the distal abdominal aorta or common iliac arteries. Surgery is the procedure of choice for diffuse, extensive, complex, multilevel, multifocal or totally occlusive atherosclerotic segments of the infrarenal abdominal aorta and iliac arteries.

3.2 Aorto-iliac stents

3.2.1 The practice of primary stenting needs to be subjected to rigorous clinical evaluation (TASC critical issue 13) and its routine use is therefore not indicated.

3.2.2 Stenting, however, improves the technical and initial clinical success in cases of residual pressure gradients, dissection of the angioplasty or elastic recoil (TASC recommendation 33).

3.2.3 Although level 1 evidence is lacking, it is accepted that primary stenting may improve outcomes in ostial disease, recurrent lesions, total occlusions and complex lesions.

3.2.4 The usefulness and cost effectiveness of multiple stents have yet to be established (TASC critical issue 12) and surgery is considered the procedure of choice when more than 2 stents are required for a lesion.

3.3 Femoro-popliteal disease (Table II)

3.4 Femoro-popliteal stents

Primary femoro-popliteal stenting is not indicated in the treatment of intermittent claudication or critical limb ischaemia. Stents may, however, play a limited role in the salvage of acute PTA failures or complications (TASC recommendation 36).

3.5 Infra-popliteal disease (Table III)

The role of infra-popliteal PTA in intermittent claudication remains to be established (TASC critical issue 15). The universally accepted indication for infra-popliteal artery PTA is limb salvage in critical limb ischaemia.

4. 2005 Guidelines for Carotid Artery Intervention

Proposed during a multidisciplinary Carotid Workshop.

***Endorsed by:* Interventional Radiological Society of South Africa, South African Society of Cardiovascular Intervention, Vascular Society of Southern Africa.**

The present standard of care of a patient presenting with a carotid artery stenosis has been defined as a result of a number of large studies.[19-25] Intervention to prevent stroke is therefore advised in:

- Symptomatic high-grade carotid stenosis of 50 - 99% as measured by comparing the extent of the stenosis to the

Table I. Morphological stratification of iliac lesions (TASC recommendation 31)

TASC type A lesions:

1. Single stenosis < 3 cm of the CIA or EIA (unilateral/bilateral).

TASC type B iliac lesions:

2. Single stenosis 3 - 10 cm in length, not extending into the CFA.
3. Total of two stenoses < 5 cm long in the CIA and/or EIA and not extending into the CFA.
4. Unilateral CIA occlusion.

TASC type C iliac lesions:

5. Bilateral 5 - 10 cm long stenosis of the CIA and/or EIA, not extending into the CFA.
6. Unilateral EIA occlusion not extending into the CFA.
7. Unilateral EIA stenosis extending into the CFA.
8. Bilateral CIA occlusion.

TASC type D iliac lesions:

9. Diffuse, multiple unilateral stenoses, involving the CIA, EIA, and CFA (usually > 10 cm).
10. Unilateral occlusion involving both the CIA and EIA.
11. Bilateral EIA occlusions.
12. Diffuse disease involving the aorta and both iliac arteries.
13. Iliac stenosis in a patient with an abdominal aortic aneurysm or other lesion requiring aortic or iliac surgery.

CIA = common iliac artery; EIA = external iliac artery; CFA =common femoral artery.

TASC recommendation 32:

Endovascular procedure is the treatment of choice for type A lesions, and surgery is the procedure of choice for type D lesions.

TASC critical issue 10:

More evidence is needed to make any firm recommendations about the best treatment for type B and C lesions.

normal internal carotid artery diameter above the lesion. Symptoms normally consist of classic carotid territory transient ischaemic attack (TIA), amaurosis fugax, or a prior stroke with either total recovery or minimal residual deficit, all of which should have occurred within the 6 months prior to intervention.

- Symptomatic patients with a lesser degree of carotid stenosis in whom best medical therapy fails to control repeated episodes of TIA or amaurosis fugax appropriate to the carotid artery stenosis, and particularly those in whom crescendo TIAs are experienced.
- Asymptomatic bilateral stenosis greater than 70% prior to coronary bypass grafting, treating the stenosis supplying the dominant hemisphere.
- Selected fit patients with asymptomatic high-grade (> 90% unilateral or > 70% bilateral) carotid artery stenosis.

Intervention is contraindicated:

- In patients with symptoms of carotid territory TIA or amaurosis fugax with less than 70% carotid stenosis in whom medical therapy has not been applied optimally.
- In the presence of ipsilateral carotid occlusion.
- After a major stroke with persistent fixed major neurological deficit (dense hemiplegia, and/or aphasia causing significant self-care impairment).
- Caution should be exercised in a patient with a symptomatic ipsilateral near-occlusive lesion.

Table II. Morphological stratification of femoro-popliteal lesions (TASC recommendation 34)

TASC type A femoro-popliteal lesions:

1. Single stenosis < 3 cm of the CFA or SFA.

TASC type B femoro-popliteal lesions:

2. Single stenosis 3 - 10 cm in length, not involving the distal popliteal artery.
3. Heavily calcified stenosis up to 3 cm in length.
4. Multiple lesions, each less than 3 cm (stenosis or occlusions).
5. Single or multiple lesions in the absence of continuous tibial runoff to improve inflow for distal surgical bypass.

TASC type C femoro-popliteal lesions:

6. Single stenosis or occlusion longer than 5 cm.
7. Multiple stenoses or occlusions, each 3 - 5 cm, with or without heavy calcification.

TASC type D femoro-popliteal lesions:

8. Complete CFA or SFA occlusions or complete popliteal and proximal trifurcation occlusions.

CFA = common femoral artery; SFA = superficial femoral artery.

TASC recommendation 35:

Endovascular procedures are the treatment of choice for type A lesions, and surgery is the procedure of choice for type D lesions.

TASC critical issue 14:

More evidence is needed to make any firm recommendations about the best treatment for types B and C lesions.

Table III. Morphological stratification of infra-popliteal lesions (TASC recommendation 93)

TASC type A infra-popliteal lesions:

1. Single stenosis shorter than 1 cm in the tibial or peroneal vessels.

TASC type B infra-popliteal lesions:

2. Multiple focal stenoses of the tibial or peroneal vessels, each less than 1 cm in length.
3. One or two focal stenoses, each less than 1 cm long, at the tibial trifurcation.
4. Short tibial or peroneal stenosis in conjunction with femoro-popliteal PTA.

TASC type C infra-popliteal lesions:

5. Stenosis 1 - 4 cm in length.
6. Occlusions 1-2 cm in length of the tibial or peroneal vessels.
7. Extensive stenosis of the tibial trifurcation.

TASC type D infra-popliteal lesions:

8. Tibial or peroneal occlusions longer than 2 cm.
9. Diffusely diseased tibial or peroneal vessels.

The above indications have largely been determined in studies comparing carotid endarterectomy (CEA) with best medical therapy. To date two studies (CAVATAS[26] and SAPPHIRE[27]) have been published comparing CEA with carotid angioplasty or stenting. The recommendation is to perform carotid angioplasty or stenting when patients are at high surgical risk or there are other factors present as listed below.

- Unfavorable anatomy for CEA (high or very low lesion).
- Recurrent disease.
- Previous radiotherapy (but not in radiotherapy-induced lesion).
- High-risk patients for surgery (clearly defined if possible)
  - CCF
  - Severe coronary artery disease
  - Severe COPD
  - Renal dysfunction.
- Associated contralateral cranial nerve injuries.
- Symptomatic common carotid or brachiocephalic artery lesions.

Patients in whom carotid angioplasty and stenting is considered to be inadvisable or even contraindicated include:

- Patients with unfavorable anatomy for angioplasty and stenting such as substantial tortuosity and an acute angle of takeoff of the carotid artery from the arch of the aorta.
- Patients with free-floating thrombus.
- Presence of echolucent plaque.
- Inability to take or contraindication to clopidogrel.

Additional issues that have not yet been adequately evaluated and would need to be taken into consideration when determining the mode of therapy:

- Accuracy of stenosis determination, particularly if carotid duplex Doppler is the only modality used to determine extent of disease.
- Plaque morphology, which has been suggested to be an independent determinant of stroke risk.

4.1 Acceptable complication rates for either CEA or endovascular treatment

Mortality: 1.5 - 3% in symptomatic patients, 0 - 1% in asymptomatic patients.

Morbidity: 3.5 - 7% stroke or disabling stroke in symptomatic and less than 2% in asymptomatic patients.

5. Renal artery stenosis

Patients with progressive atherosclerotic renal vascular disease are a heterogeneous group with different presentations, different spectrum of pathologies and response to treatment. The debate regarding the best treatment is ongoing and it is hoped that the ASTRAL Trial in the UK and the STAR Trial in the Netherlands will provide much-needed clinical evidence to determine whether revascularisation by angioplasty carries any benefit over aggressive best medical therapy.

When considering guidelines for renal artery intervention, the following known facts must be taken into account:

- Atherosclerotic renovascular disease is a combination of hypertension and ischaemic nephropathy where hypoperfusion from renal artery stenosis is in most cases of minor significance.[28]
- The combination of essential and renovascular hypertension is frequently present and renal revascularisation will have no effect on the intrarenal changes of hypertension or on intrarenal arteriosclerosis.[29]
- Progression of renal artery stenosis to complete occlusion and renal failure takes place at a much lower rate than previous angiographic studies had suggested.[30]
- The majority of patients with progressive atherosclerotic renal vascular disease will die from other vascular causes before developing end-stage renal failure.[31]
- Renal artery interventions have a significant peri-procedural risk including athero-embolism.[32,33]
- Three randomised trials comparing renal angioplasty with medical treatment showed only minimal differences in blood pressure between PTA and best medical therapy.[34-36]
- Recent studies on renal artery stenting in ischaemic

nephropathy report an improvement of renal function in 22 - 41% of patients (average 33%) with no change occurring in about 50% of patients.[37-43]

- A randomised trial comparing renal PTA with PTA and stenting showed higher patency rates after stenting, but no difference in the effects on blood pressure and renal function.[44]
- The patient groups most likely to benefit from renal revascularisation are given in Table IV.

Table IV. Indications for renal PTA and stenting.[45]

Progressive renal failure of short duration (< 6 months)
Pulmonary oedema and refractory congestive cardiac failure
Severe renal failure precipitated by ACE inhibitor treatment
Refractory hypertension
Severe renal artery stenosis (> 80%)[46]
Renal length (> 8 cm)

It is imperative not to intervene for anatomical renal artery stenosis without adequate indications; this is particularly the case in incidentally discovered renal artery stenosis.[47]

6. Trauma

There are currently no accepted guidelines for the endovascular management of trauma, but these techniques are already used in 3 ways in managing vascular trauma, viz.:

- **To obtain definite haemostasis.** Embolisation is a well-established technique for the control of haemorrhage from small and medium-sized vessels. It has become the standard method for managing significant bleeding following pelvic fractures. It is also used to control bleeding from penetrating and blunt trauma of the liver, spleen and kidneys.[48-51]
- **To obtain vascular control.** Temporary balloon occlusion for inflow control of damaged blood vessels until such time as permanent repair can be achieved.[52]
- **For vascular repair.** The most important indication for stent grafts is inaccessible vessels in anatomically challenging locations where stent graft repair would obviate the need for major surgical procedures. The use of endovascular repair in vascular trauma has been described in injuries of the thoracic aorta, thoracic outlet vessels, internal carotid and vertebral arteries.[53-56]

Long-term durability remains a major concern in endovascular management of peripheral vascular disease. This is of concern in the younger population who are the main victims of trauma. Although the results of endovascular treatment look promising, long-term follow-up and randomised prospective trials comparing standard surgery with endovascular grafting will be necessary before the generalised use of these devices can be recommended.

7. Thrombolytic therapy

7.1 Arterial thrombolysis

Catheter-directed thrombolysis has the theoretical and practical advantages over thrombo-embolectomy of decreasing endothelial trauma and, in conjunction with angiographic control, uncovering the underlying lesion(s) and visualising the run-off vessels.[57]

7.2 Indications

7.2.1 Acute native arterial occlusions. There is currently no evidence that thrombolysis is preferable to surgery for the initial universal treatment of acute limb ischaemia. There is no overall difference in limb salvage or death at 1 year between initial surgery and initial thrombolysis. Thrombolysis may be associated with a higher risk of ongoing limb ischaemia, and of haemorrhagic complications including stroke.[58] However, intra-arterial thrombolysis may be considered for the treatment of thrombotic or embolic occlusions in patients with Rutherford catergory I and IIa limbs (threatened, but salvageable, without paralysis, mild sensory changes only).[57] Surgical intervention is recommended for patients with threatened limbs accompanied by more significant motor and sensory changes (category IIb). Non-salvageable limbs (category III) will require primary amputation.

Thrombolysis is recommended for the initial treatment method for occlusion of distal run-off arteries.

7.2.2 Acute occlusion of an established bypass graft. Thrombolytic therapy is preferably given within 14 days of occlusion.[59-61] Chronic occlusions (> 14 days) have a better outcome with surgery.[61] This is irrespective of the type of graft occluded (viz. prosthetic or autogenous bypass graft).[62]

Occlusion within 14 days of graft insertion should rather be treated surgically.

7.2.3 Acute thrombosis at the site of an intervention.[63]

7.2.4 Acute mesenteric occlusion (arterial and venous).[63]

7.2.5 Acute embolic occlusion of the renal artery. Thrombolysis in this setting should be used within 90 minutes of the renal artery occluding.

7.2.6 Thrombosed dialysis access grafts or fistulas.[64]

7.2.7 Preoperative thrombolysis of thrombosed popliteal arterial aneurysms[65,66] to clear occluded distal run-off vessels.

7.2.8 As an adjunct to the treatment of chronic arterial occlusions.[67]

7.3 Contraindications[63]

7.3.1 Acutely threatened limb with advanced sensory or motor deficits and proximal occlusion.

7.3.2 Cerebrovascular accident (including neurosurgery or transient ischaemic attacks) within 3 months.

7.3.3 Active bleeding diathesis.

7.3.4 Gastrointestinal bleeding within 10 days.

7.3.5 Major non-vascular surgery, eye surgery or trauma within 10 days.

7.3.6 Severe, uncontrolled hypertension.

Relative contraindications include pregnancy, hepatic failure, bacterial endocarditis and diabetic haemorrhagic retinopathy.

An increased risk of adverse bleeding is associated with increasing age, female gender, concomitant anticoagulant use (warfarin, aspirin), graft occlusion and Fonteine class III and IV ischaemia.[68]

Thrombolytic agents currently in use include streptokinase, urokinase, alteplase and reteplase. The alternative or concomitant use of glycoprotein IIb/IIIa inhibitors is currently under investigation. Intravenous administration of high doses of currently available thrombolytic agents should no longer be used for the treatment of arterial occlusion in the leg. Intra-thrombus infusion should be used (TASC recommen- dations 58 and 59).[69]

The use of mechanical thrombectomy devices for thrombus debulking as a stand-alone therapy or as an adjunct to thrombolysis is well described, particularly for haemodialysis graft occlusion, and more recently peripheral arterial occlusions.[70] Owing to the expense and difficulty of using these devices, their use is recommended in patients in whom both thrombolysis and surgery would be contraindicated, or who require rapid thrombus debulking.

7.4 Venous thrombolysis

7.4.1 Indications

7.4.1.1 Deep venous thrombosis (DVT). Although there is no conclusive evidence to date that thrombolytic therapy for the treatment of venous thrombosis has any significant advantage over anticoagulation therapy,[71] there is growing evidence that early treatment of DVT with thrombolysis does result in the preservation of valve function, a reduction of the incidence of post-phlebetic syndrome and improved quality of life.[72] Catheter-directed thrombolysis can be considered as a safe and effective method of initial treatment for symptomatic acute proximal lower-extremity DVT.[73,74]

7.4.1.2 Phlegmasia cerulea dolens.

7.4.1.3 Thrombotic superior vena caval occlusion.

7.4.1.4 Axillary/subclavian vein thrombosis in selected cases.[75]

7.4.1.5 Acute renal vein thrombosis in a transplanted kidney.

7.4.1.6 Prevention of pulmonary embolism in an unstable patient.

7.4.2 Caution

7.4.2.1 Local (intra-thrombus), catheter-directed thrombolysis is superior to systemic administration of thrombolytic therapy treatment.

7.4.2.2 It is not indicated for distal DVT, and has its greatest advantage in proximal (ileofemoral) DVT.

7.4.2.3 The same contraindications to venous thrombolytic therapy apply as in arterial thrombolytic therapy.

7.4.2.4 Venous thrombolysis may have the greatest advantage in younger patients with extensive ileofemoral thrombosis where the longstanding sequelae of the post-thrombotic syndrome are worst.

7.5 Use of vena cava filters

Vena cava filter placement should be considered in the following situations:[76]

- Contraindication to anticoagulation or thrombolysis.
- Complications as a result of anticoagulation or thrombolysis.
- Failure of anticoagulation.
- Prophylaxis against pulmonary embolism.

Absolute contraindications to vena cava filter placement include:

- Uncorrectable coagulopathy.
- Systemic infection with bacteraemia and positive blood cultures.

The use of retrievable or temporary filters should be considered as an alternative to permanent filter placement in patients requiring protection for a limited period of time.

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