

Outflow reconstruction of the lower extremity in chronic venous obstructive disease

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VALORISATION

Yearly 1-2 in 1.000 individuals from the general population of Western countries will suffer a deep venous thrombosis (DVT). In the elderly the incidence can be as high as 1 in every 100 individuals. Up to half of DVT patients will develop the post-thrombotic syndrome (PTS). With the aging of the population as a whole, both the medical and economic impact of DVT and PTS will gravely increase. However, in both the medical world and layman media PTS is an underappreciated subject. Before the advent of deep venous stenting there was no causative treatment modality. Relatively effective symptom reduction therapy was possible in many PTS patients, mostly by use of compression garments and sometimes analgesics. However, some still suffered incapacitating symptoms, e.g. gross lower limb swelling and debilitating pain during mobilization. Moreover, many PTS patients never received this minimal level of care, and thus were undertreated. PTA and stenting in venous disease was introduced as a routine daily practice at the end of the 1990's in a number of centres worldwide, most notably in the United States of America. Since then it has slowly gained attention and implementation in more and more specialized centres worldwide. However, widespread knowledge about this treatment is still lacking in general medical daily care. This thesis is characterized by a number of unique studies, i.e. the description of the first clinical results of a specially designed dedicated venous stent (the sinus Venous stent) in chapter 4 and the first study reporting a mid-sized population treated by the combination of PTA, stenting, endophlebectomy and AV-fistula creation, offered as a standardized intervention in chapter 7. Moreover, the study in chapter 8 describing the clinical outcome of the total population of treated patients is one of the largest series available in current literature.

Therefore, this thesis adds a substantial body of data in favour of interventional treatment of PTS and IVCS. Many patients who are currently not treated for the underlying cause of their venous symptoms can benefit from PTA and stenting. As chronic treatment with medication and compression garments can be very expensive, especially in cases of venous ulceration, PTA and stenting might drastically reduce healthcare costs on the long term.

Target population in and outside the medical field

Primarily the results of PTA and stenting in chronic venous obstructive disease are of special importance to (vascular) surgeons, (interventional) radiologists, dermatologists, phlebologists, internists, geriatrists and general practitioners. Moreover, anyone in the field of medical device development, be it researchers or medical device companies, can find new targets or support for their products. A whole new field within the specialties of surgery and radiology are explored in this thesis. Also, government bodies and health insurance companies might be interested in the role of PTA and stenting in combating ever increasing healthcare costs, as this treatment may prevent the high costs from decades of conservative treatment.

Activities and implementations resulting from this thesis

The sole treatment by use of PTA and stenting has gained some attention during the last few years. However the routine use of endophlebectomy and AV-fistulas in the most severe cases of PTS is a relative novelty. Other centres worldwide might be moved to start using this treatment themselves, or find alternative ways to treat these gravely affected patients. Moreover, the use of dedicated venous stents can be implemented in many already ongoing or in new venous obstruction treatment protocols. Furthermore, these encouraging results with the first generation of dedicated venous stents can motivate medical corporations to invest in better tools, stents and other devices. However, the most important activity for the near future will be to bring the knowledge and the clinical potential of this treatment modality in the attention of the medical world as a whole.

Innovation

The most important innovation resulting from this thesis should be the improvement of care of patients suffering from deep venous pathology. Every patient suffering from PTS should have the opportunity to be evaluated by a physician knowledgeable about this subject, and if eligible be treated accordingly. Furthermore, the severity of the disease described in this thesis might add to the discussion of how DVT should be managed. As already stated many patients treated by conservative therapy for DVT (anticoagulation and compression) will develop PTS. The best management of PTS includes the prevention of PTS at the time of the initial DVT. Currently a number of thrombus removal techniques are under research, and some are already implement in specialized centres worldwide. PTA and stenting as a primary treatment might have a role in DVT prevention in IVCS patients. In their classical 1957 paper the authors May and Thurner recognized the role of the common iliac vein compression in left sided DVT pathogenesis, and indeed this was already hypothesized by Rudolf Virchow a century earlier. Treating this iliac compression, in patients who already suffer from chronic venous obstructive symptomatology, may have a profound effect in preventing DVT, and subsequent PTS development. The same can be said about the prevention of secondary DVT in PTS patient, however in these cases the thrombogenic effect of stenting itself needs to be taken into consideration.

Realisation of future activities and research

Convincing the medical world as a whole to take treatment of venous disease to the next level will be the most important aim of future research. To achieve this randomized controlled trials and great registries are needed. Development of a RCT protocol is currently taking place in our own centre. The American Venous Forum has already started a registry aimed at venous stenting in the United States of America. An European counterpart should be appropriate.

In order to improve the current treatment strategies, a number of subjects need to be studied more in-depth. Firstly, the protocol of post-interventional anticoagulation should be investigated. Currently, anticoagulation is not able to prevent a significant number of rethrombosis. Moreover, treatment might be too aggressive in a great number

of patients, especially those without a prior thrombotic event; the IVCS patients. Secondly, even though the introduction of dedicated venous stent designs has helped in attacking a number of specific stent related complications, these complications are still present after a significant number of interventions. Further improvement of stent design might be helpful in this respect. Thirdly, the use of endophlebectomy and temporary AV-fistula creation has helped us in providing a causative treatment for even those PTS patients most severely affected by post-thrombotic vein damage. However, these operations are characterized by specific complications, especially the occurrence of stenoses at the level of the treated vein and the frequently problematic wound healing. Ideally these complications can be avoided. Options might be the preventive use of VAC therapy aimed at the wound healing disorders, and the use of special intra-operatively deployable inlays for the endophlebecomized common femoral vein.

In conclusion it can be stated that the world of deep venous reconstructions is still in its infancy. Much efforts will be needed to reach the next stage, but this has the potential to revolutionize the field of vein disease.