Short term and intermediate term patency of synthetic graft material in aorto-iliac diseases a comparative study.

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ABSTRACT

Aorto-iliac disease is an important entity and its management if far from satisfactory even in the era of medical marvels.

The complexity of its treatment lies in every aspect of the disease management, from difficulty in early diagnosis to absence of ideal reconstructive materials as there is a lack of autogenous vascular substitute due to mere comparative large size of the vessels involved.

Material and methods: In the various group, the patients included in study were followed up and studied for patency of the various graft materials using following imaging modalities:

- Full physical examination.
- Duplex scan (mostly for peripheral vascular disease)
- Cardiac CT Scan- 128 slice (for coronary disease)
- Angiography (conventional as well as CAT)
- CT aortography

Observation: It was noticed that Dacron grafts had an inferior patency rate of 87.5% after 1 year where as PTFE grafts at our centre presented with a patency rate of 92 % after a period of 1 year.

Discussion: In our population Dacron grafts can serve as a good alternative as they are more economical than their PTFE counterpart.

INTRODUCTION

Peripheral artery occlusive disease, commonly referred to as peripheral arterial disease (PAD) refers to obstruction or deterioration of arteries other than those supplying the heart and within the brain.

PAD is more prevalent in non–white population explained by an increased incidence of co-morbid diseases.

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The prevalence of PAD increases with advancing age\(^3\) and it’s a well proven fact, but still PAD remains largely under detected due to silent progression\(^2\) and lack of knowledge amongst the sufferers.

South-east Asian population is currently burdened with metabolic diseases, India being a frontrunner and earning a well deserved title of diabetes capital of the world\(^3\).

Metabolic diseases are harbinger of myriad complications, eminent one being peripheral arterial disease, which is a continuum of cardiovascular diseases and implicator of each others existence.

Aorto-iliac disease is an important entity and its management if far from satisfactory even in the era of medical marvels.

The complexity of its treatment lies in every aspect of the disease management, from difficulty in early diagnosis to absence of ideal reconstructive materials as there is a lack of autogenous vascular substitute due to mere comparative large size of the vessels involved.

The answer to this problem lies with the usage of synthetic graft materials.

Currently, expanded polytetrafluoroethylene (ePTFE), polyethylene terephthalate (Dacron\(^\circ\)) and polyurethane are used to fabricate synthetic vascular grafts.

Synthetic materials have been employed in vascular graft design for a variety of reasons, mainly due to the ease and flexibility of tailoring their mechanical properties. One such example is ePTFE, a porous polymer with an electronegative luminal surface that is not degradable.

The purpose of the study is to compare the various conduits generally used in practice for revascularization and their functioning over a period of 2 years, both retrospectively and prospectively, irrespective of their site of grafting.

MATERIAL AND METHOD

All patient older than 18 years admitted in surgery department L.L.R. Hospital and department of cardiovascular and thoracic surgery LPS institute Kanpur with vascular diseases from Dec. 2015 to Oct 2017 were including in the study following procedure.

Graft failure is considered when there is either recurrence of initial symptoms which can be attributed to the dysfunctioning of a particular conduit, or direct imaging of the conduit which states its occlusion.

Stenosis of the conduit was not considered as criteria until and unless there was complete occlusion of the conduits.

Inclusion criteria – patients having following criteria were included in the study -

- Peripheral vascular disease
  1. Chronic peripheral vascular disease
     a) Infra-inguinal
     b) Aortic disease –operative aneurysmal and non –aneurysmal
     c) Upper limb peripheral vascular disease
  2. Medium and large vessel disease
  3. Salvageable limb threatened marginally
  4. TASC II (Trans-Atlantic Inter-Society Consensus) Type C and D lesions
  5. Presence of critical limb ischemia (Fontaine III, Rutherford 4)

Exclusion criteria - patients having following criteria will not be included in the study -

- Age >80 years;
- Small vessel disease
- In-operable patients
- Unsalvageable limbs
- Abdominal aortic aneurysms less than 5.5 cm
- CAD or PVD with mesenteric ischemia
- CAD or PVD with neurological disorder
- CAD or PVD with other traumatic injury.
- Unstable angina or myocardial infarction <2 and <7 days before surgery, respectively;
- Previous or concurrent cardiac surgery;
- Need for continued antithrombotic drug therapy; an increased risk of bleeding; impaired renal or hepatic function;
- Concomitant severe disease;
- Inability to repeat coronary angiography due to allergy to contrast agent.
- Moribund patients

COLLECTION OF DATA:

The study was conducted on the hospital-based time bound in all those cases who satisfied the inclusion criteria. The data was collected from detailed history, clinical examination, and investigations (haematological investigations and radiological parameters) on the patients.

PERIOD OF FOLLOW UP:

- OPD basis in patients
- IPD basis

Patients were evaluated during the hospital stay, then on 6 months and 1 year or observed if presenting with complications.

After the documentation of conduit occlusion / graft failure, the subjects were not further followed.

In the various group, the patients included in study were followed up and studied for patency of the various graft materials using following imaging modalities:

- Full physical examination.
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- Cardiac CT Scan- 128 slice (for coronary disease)
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OBSERVATION

In the case of non-coronary diseases there were total of 21 cases that were encountered.

5 were females and 16 were males and they were broadly categorized under peripheral vascular disease in which synthetic grafts were used. A comparison was done between use of PTFE graft and Dacron (polyethylene terephthalate) on the basis of short and intermediate term patency. (Figure 1)
Age distribution of the 21 cases studies was as following (table 1):

<table>
<thead>
<tr>
<th>GENDER DISTRIBUTION</th>
<th>MALE</th>
<th>FEMALE</th>
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<tr>
<td></td>
<td>16</td>
<td>5</td>
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Out of the 21 cases studied, majority of them were of infra-renal aorto-iliac disease accounting for a total of 16 cases, one case of arch of aorta occlusion, one case of supra-renal aortic block, one case of right subclavian pseudo-aneurysm, one case of abdominal aorta disease and one case of right common iliac occlusion was observed. (figure 2)

In the above mentioned conditions there were requirements to achieve a bypass to maintain blood flow to the distal part of the vessel or bypass the diseased segment. To establish such a bypass, Dacron as well as PTFE synthetic grafts were used.

A total of 13 PTFE and 8 DACRON grafts were used as bypass (figure 3)

After placement of these grafts, the patient receiving the grafts were followed for a period of 2 years, which consisted of follow at 1 month for short term patency of the graft and 1 year follow up to assess an intermediate term patency of the grafted material.
It was observed that with Dacron, out of the 8 conduits grafted there was a failure of one graft that was due to graft infection, which took place at a period of 1 month, thus being termed as early graft failure, rest of the implanted grafts were all patent after the period of 1 year (figure 4).

In case of the 13 PTFE grafts that were implanted, none of the grafts showed graft failure after a period of one month, but one graft failure took place after a period of 1 year (figure 5).

DISCUSSION

Vascular disorders have a huge impact on a patient’s life. These disorders are associated with great morbidity as well as mortality.

A vascular disorder encompasses a huge spectrum of diseases, which in the end is responsible for organ hypo perfusion and dysfunction.

In our study we addressed this mammoth problem of vascular disease, which include the follow up study of 21 cases of non-coronary vascular diseases which encompass the diseases of aorta and other peripheral vessels, mainly the aorto-iliac vessels.

Our study is a comparative study which discusses the various conduits that were available to us for revascularisation of the diseased organ and used to counter-attack this ever so growing situation of vascular disease.

We also compared the various available conduits to us to know which is superior than its counterparts in terms of providing a long symptom free period post-operatively to the patient and also prevent mortality.

Long-term conduit patency is the key factor for the success of the procedure

In the non-coronary component of our study, we observed 21 cases with peripheral vascular disease which underwent operative interventions and in such cases synthetic grafts were used and we compared between Dacron and PTFE grafts. 5 were females and 16 were males. Majority of them were of infra-renal aorto-iliac disease accounting for a total of 16 cases. Most commonly age group affected by peripheral vascular disease is between 50 to 59 years.

In peripheral vascular bypass surgery different synthetic materials are available for bypass grafting. It is unclear which of the two commonly used materials, polytetrafluoroethylene (PTFE) or polyester (Dacron®) grafts, is to be preferred.
It was observed that with Dacron, out of the 8 conduits grafted there was a failure of one graft that was due to graft infection, which took place at a period of 1 month, thus being termed as early graft failure, rest of the implanted grafts were all patent after the period of 1 year.

In case of the 13 PTFE grafts that were implanted, none of the grafts showed graft failure after a period of one month, but one graft failure took place after a period of 1 year.

It was noticed that Dacron grafts had an inferior patency rate of 87.5% after 1 year where as PTFE grafts at our centre presented with a patency rate of 92 % after a period of 1 year.

The surgical options for AI occlusive disease include endarterectomy, aortoiliac bypass, aortobifemoral bypass and extra-anatomical bypass in the form of iliofemoral, bifemoral and axillofemoral bypass grafting. Given its superior long term patency rates, aortobifemoral grafting is currently considered the revascularization procedure of choice.

Post et al studied patency of Dacron and thin walled PTFE for above-knee grafts in 203 patients. there was no difference regarding primary and secondary patency or limb salvage between Dacron and PTFE. The primary 3-year patency for Dacron grafts was 64% (95% confidence interval [C.I.] 55–74%) and for PTFE grafts 61% (C.I. 49–72%).

Jensen et al found The two-year primary patency rates for Dacron and PTFE were 70% and 57% (p=0.02)

Manfred R. Prager, MD, Thomas Hoblaj, et al found Primary patency rates were 77% for GEL-D, 78% for COL-D, and 79% for PTFE at 8 years.

In case of the non-coronary vascular disease the various studies shows different findings. In our study the results favoured PTFE grafts for better patency in comparison to Dacron grafts. But the difference between the two was not substantially relevant and both the materials have their pros and cons.

In our population Dacron grafts can serve as a good alternative as they are more economical than their PTFE counterpart.

CONCLUSION

On the basis of observation of the clinical profiles of the cases with the evaluation of the various conduits by radiological methods mainly angiography and duplex scan the following conclusions were drawn:-

1. Vascular disorders are associated with great morbidity as well as mortality.
2. The disease is more common in male population and has a definitive relationship with diabetes mellitus and hypertension as cases suffering from such co-morbidities had more extensive disease with more severe involvement of vascular beds.
3. Although peripheral vascular diseases are a common entity and the prevalence of the disease in the population is noteworthy, the amount of people receiving an active operative intervention still remain less.
4. In case of peripheral arterial disease we mostly studied the population presenting with an aorto-iliac disease and most of them were treated with aortobifemoral grafts consisting of either Dacron or PTFE material
5. PTFE had a better patency as compared to Dacron material.
6. Synthetic grafts have decreased the requirements of an autologus graft and provide a good treatment option for patients as there is paucity of autologous grafts to be positioned at such a position.
7. After revascularisation the morbidity and mortality of the patient is significantly decreased and thus operative management is warranted against medical management in a selective group of patients

Surgical revascularization remains a cornerstone of treatment for advanced, symptomatic PAD. The emergence of percutaneous techniques has expanded the armamentarium but has not altered the fundamental principles of revascularization nor the indications for intervention. Rather, the emphasis is placed on patient selection for these complementary modalities. Patient-specific factors are critical in selecting the most efficacious and durable outcome, with particular importance placed on comorbid conditions, estimated life expectancy, functional status, pattern of disease, and availability of conduits.

REFERENCES

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