LONG TERM RESULTS OF OPEN ABDOMINAL AORTIC ANEURYSM REPAIR

Thesis

From 1st January 2011 to 31st December 2013

Under the guidance of

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By

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Travancore, an erstwhile province of pre-independent India, was ruled by Sree Chitra Tirunal Maharajah until the country became independent in 1947. The Government of India took over the province after the independence.

Known for their munificence, the Maharajah and members of the royal family of Travancore considered themselves 'dasas' (servants) of Lord Padmanabha, the reigning deity of Travancore. Interestingly, they wore a turban instead of a crown as a mark of respect to Lord Padmanabha. Their philanthropy finds expression in their countless contributions to the country, then and now.

On a visit to a super-specialty hospital in Europe, Sree Chitra Tirunal Maharajah was seized with a deep desire to establish a similar institution in Kerala. Those were the times when tertiary cares in cardiovascular and neurological diseases were not available in the State.

In the summer of 1974, the Maharajah's dream was fulfilled when the royal family made a gift that carried in its womb the beginnings of what later turned out to be the Sree Chitra Tirunal Institute for Medical Sciences & Technology. About this time, Dr. M.S. Valiathan, trained abroad in surgery and biomedical science, returned to India to guide the destiny of the Institute. Supported magnificently by Shri. C. Achutha Menon, the then chief minister of Kerala, the Government of Kerala took the unusual step of placing the centre under the Department of Science and Technology in the State.

The Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram is an Institute of National Importance established by an Act of the Indian Parliament. It is an autonomous Institute under the administrative control of the Department of Science and Technology, Government of India.

The Institute signifies the convergence of medical sciences and technology and its mission is to enable the indigenous growth of biomedical technology, besides demonstrating high standards of patient care in medical specialties and evolving postgraduate training programs in advanced medical specialties, biomedical engineering and technology, as well as in public health.

BIO – MEDICAL TECHNOLOGY WING

SCTIMST

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/10/2013 **Dr Shashidhar K P**

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DECLARATION

I, **Shashidhar K P**, hereby declare that the project in this book was undertaken by me under the supervision of Prof M Unnikrishnan, MCh, Professor and Head of the Division of Vascular Surgery, Department of CVTS, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram.

Shashidhar K P

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Forwarded

The candidate, **Shashidhar K P**, has carried out the minimum required work in this project.

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CERTIFICATE

Certified that this is bonafide record of ***Shashidhar K P,*** *the work done at Vascular Surgery division, Department of CVTS, as part of MCh programme, at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, for a period of three year from 1ST January 2011 to 31ST December 2013.*

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TITLE

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INTRODUCTION

Of all the diverse atherosclerotic expressions in human body, abdominal aortic aneurysm (AAA) with its concerted refinements in diagnosis and therapeutic paradigm over time is considered the flagship of glorious modern vascular surgical practice. Of all the arterial aneurysms in the body, abdominal aortic aneurysms the most common aneurysm and its prevalence is approximately 75%. Abdominal aortic aneurysm is the 13th cause of death in developed countries and prevalent across the globe, eventually leads to fatal rupture if not intervened in or on time. Similarly elective repair, be it open surgical or state of the art endovascular has a low mortality risk in contradistinction to emergent for ruptured aneurysm. SVS and ICVS have formulated 5.5 cms size as the threshold for intervention/repair. There is paradigm shift towards endovascular repair of abdominal aortic aneurysm ever since Juan C parodi introduced the revolutionary minimally invasive technique in the early 1990s. But open repair of is still the gold standard and most durable.

AIMS OF THE STUDY

1) To determine the predictors of mortality in open abdominal aortic aneurysm repair.

2) To determine the long-term survival of open abdominal aortic aneurysm repair.

REVIEW OF LITERATURE

Arterial aneurysms have been known to physicians for a long time. The Ebers papyrus (2000 BC) mentions about aneurysms. Galen (131-200 AD) also described aneurysms.[1] The ancient Indian surgeon Sushruta in his book Sushruta Samhita describes vascular malformations including aneurysms (Chapter 11, Nidana Stana, Slokas 8 and 9)[2]. The earliest report of surgery for an aneurysm is from the 3rd century, and numerous surgeons reported performing ligation of feeder and runoff vessels from aneurysms in the 17^{th} and 18^{th} centuries.

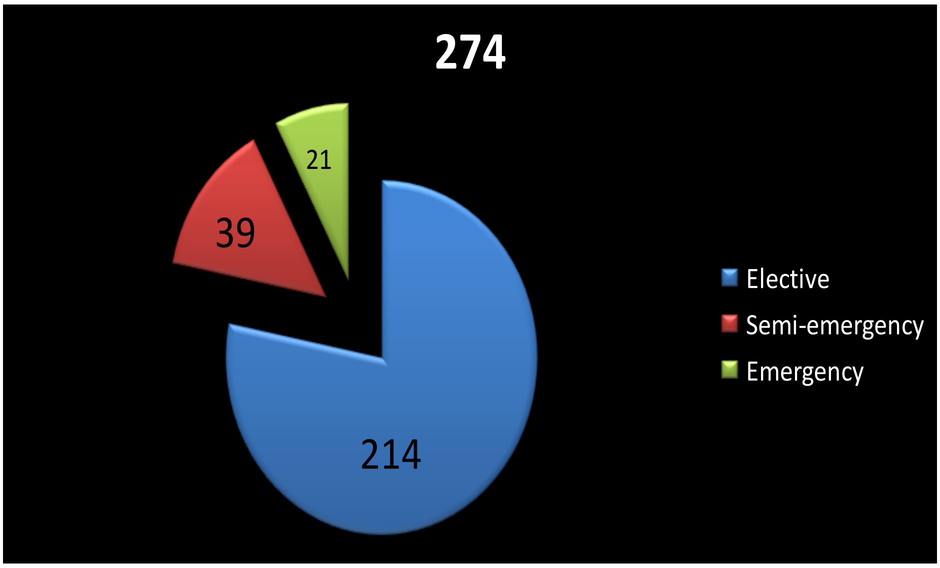
With John Hunter (1728-1793), surgery began to emerge as a scientific discipline on the basis of anatomy and physiology. On December 12, 1785, he ligated the superficial femoral artery high in the thigh in the area now known as Hunter's canal to treat a popliteal aneurysm. The patient did well, the aneurysm shrunk to a hard knot, and the limb survived. Astley Cooper (1768-1841) made contributions in many fields of surgery, but his name is linked permanently to advances in vascular surgery. His operation on a leaking iliac aneurysm was the first recorded case of ligation of the aorta for aneurysm. Matas, in 1888, performed the first definitive repair, endoaneurysmorrhaphy, by ligating the braches of a brachial artery aneurysm from inside the aneurysm sac.[3] However it was not until suture repair of arteries became feasible that aneurysms preservation of blood flow. The first such operation was performed by Dubost in 1951 when he replaced an abdominal aortic aneurysm (AAA) with a thoracic aortic homograft harvested from a recently deceased 20-year-old. This patient lived for 8 years postoperatively.[4] In 1954, Blakemore and Voorhees published their series of 17 aortic and 1 popliteal aneurysms repaired with Vinyon "N" cloth prostheses (with materials provided by the Union Carbide and Carbon Corporation).[5] This work launched the modern age of synthetic replacement of aneurysms. The following year, Cooley and DeBakey presented their work on repair of thoracic aneurysms with homografts.[6]

Thoracic and thoracoabdominal aneurysms have presented a challenge for many years. DeBakey and Cooley reported the first case of a successful resection and graft, of a fusiform, thoracic aneurysm that was performed January 5th 1953, since that time, all sections of the thoracic aorta from arch to the diaphragm have been resected successfully and replaced by grafts of various sorts.[7] In 1974, Stanley Crawford reported his experience. In the later cases, the graft was inserted inside the aneurysm with reattachment of visceral branch origins directly to an opening in the graft wall, which is the inclusion technique that we use today.[8] Open repair refined over the next 4 decades, and in present day it is one of the safest procedure with minimal morbidity and mortality.

Since its introduction minimal invasive endovascular aneurysm repair (EVAR) by parodi et al.[9] in 1991, EVAR has become a safe and increasingly common alternative to traditional open aneurysm repair. Numerous studies have demonstrated a high rate of technical success and relatively low morbidity rate with EVAR.[10] EVAR is not currently applicable to all patients, due to difficult anatomy.[11] As a result, open AAA repair is still the gold standard.

MATERIAL AND METHODS

From June 1998 to August 2013, 274 consecutive open AAA repair were included in the study. Patients with both infrarenal and juxtarenal aneurysms were included. Those patients with suprarenal, type IV thoracoabdominal aneurysms and those who underwent endovascular aneurysm repair were excluded. Among these 274, elective procedure for intact aneurysms was performed in 214, urgent procedures for contained/threatened rupture in 39 and emergent repair in 21 for free rupture.



Demographic, preoperative, perioperative, postoperative data and follow up were recorded from review of patient records and institutional electronic medical records. Patients undergoing elective repair underwent diagnostic workup with ultrasound abdomen, computed tomography(CT) angiogram/magnetic resonance angiogram, and work up for fitness included, complete haemogram, liver function tests, renal function tests, coagulation profile, chest X-ray, pulmonary function test, electrocardiogram, echocardiogram and coronary arteriogram. Renal insufficiency was defined as a creatinine level of 1.5 mg/dL or more, reverse staging in the form of stenting or coronary artery bypass was mandated for significant/symptomatic coronary artery disease prior to elective AAA repair in 21 (9.8%) of patients.

Procedure: Supine position with parts prepared from nipple to midthigh, ryle's tube, urinary catheter, central & peripheral venous access taken. Abdomen accessed through midline xipho-pubic laparotomy. Then transverse colon was put upwards and small bowel to the right covered in wet towel. Posterior peritoneum overlying aneurysm incised. Then dissection is started between duodenum and inferior mesenteric vein on top and continued onto right common iliac artery avoiding injury to duodenum and ureter. Left common iliac artery is dissected and clamp space crested avoiding injury to sympathetic fibers. Left renal vein retracted above to decide clamp space. Test clamp applied to confirm on clamp space and graft material, type & length selected. Protective medicines – Mannitol, Fluids, and two suctions kept ready.

Then heparinised at 1 mg/kg, Clamp aorta at predetermined space and clamp both common iliac arteries with bulldogs. Aortotomy is done from centre of aneurysm extending proximally to neck, distally up to bifurcation. Evacuate thrombus, send for culture sensitivity & gram stain. Then decide suture ligation/reimplantation of inferior mesenteric artery if open. Suture ligate all lumbar's/median sacral arteries with ticron 3-0. Proximal T cut and stay sutures taken with ticron. Proximal anastomosis done with Prolene 3-0/4-0 (Felt optional). Complete anastomosis and release clamps ratchet by ratchet & checks proximal suture line. Distal T-cut and stay sutures taken. Anastomosis using prolene 4-0 double stranded technique. De-air and complete the suture line. Perfuse each limb one after the other, cauterize aneurysm cut margins and wrap wall around graft with ticron stitches. Peritoneum closure with chromic catgut and abdomen closed in layers.

Perioperative mortality, early and long-term events were identified through review of patient records and the hospital's electronic medical records. Additional information beyond 10 years regarding patient survival and death was obtained from telephonic and letter communications. Aneurysm-related mortality included death from any cause within 30 days of the primary AAA procedure or any secondary procedure related to aneurysm. Finally, secondary graft-related interventions and non-graft related interventions were determined, as well as time, method, and success of such reinterventions. Overall survival (Kaplan-Meier test), factors predictive of these end points were determined by univariate and multivariate analysis.

Statistical analysis.

Long term survival was assessed by Kaplan-Meier analysis. Predictors of long term mortality were analysed with univariate (Chi-square) and multivariate (Cox regression) analysis.

Variables used in the multivariate analysis included

1) Age
2) Sex
3) Smoking
4) Hyperlipidemia
5) Hypertension
6) Diabetes
7) Chronic obstructive pulmonary disease
8) Coronary artery disease
9) Renal insufficiency
10) Clamp placement (Infrarenal or Juxtarenal)
11) Type of graft (tube or bifurcated)
12) Reinterventions

P value of <0.05 was considered significant for all statistical analysis.

RESULTS

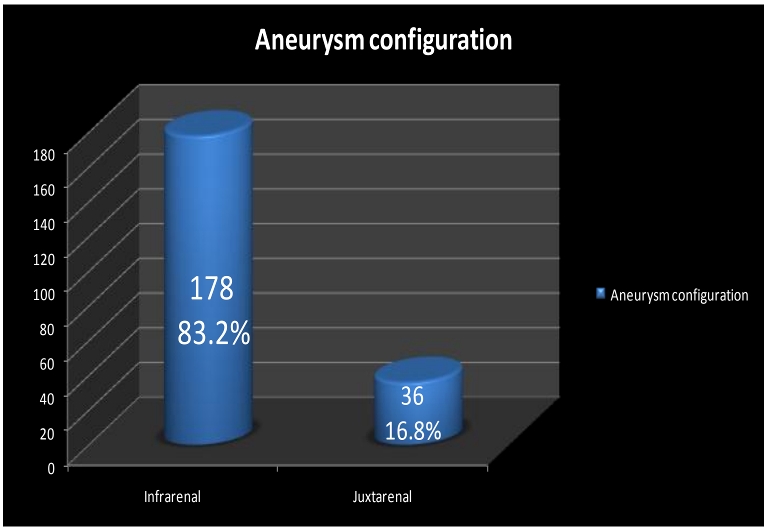
During the study period, 274 patients underwent open AAA repair, among whom 214 patients underwent elective for intact aneurysms, 39 urgent repairs for contained/threatened rupture and 21 emergent for free rupture. Further analysis pertained to elective cohort only. Demographic and clinical factors are summarized in Table I.

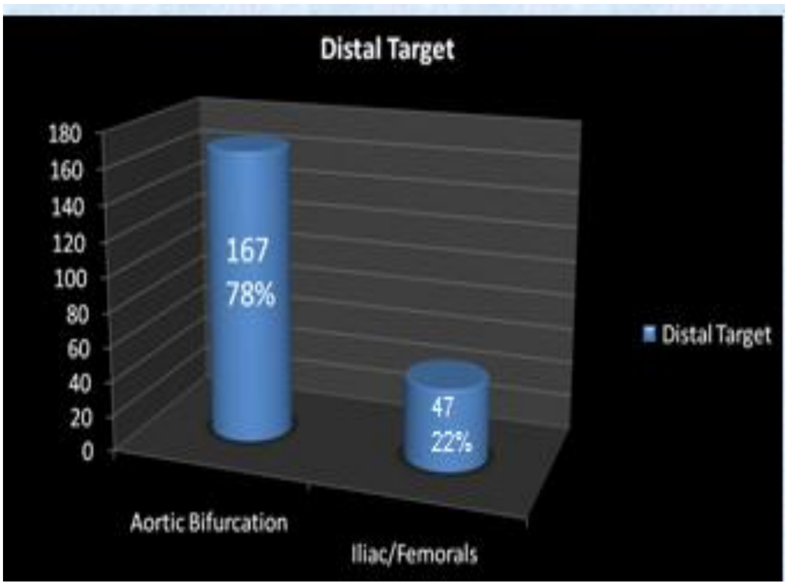
Table I . Demographic and clinical data

No. of patients	n=214
Mean age in yrs (range)	63.70 (21-85)
Male: Female	14.3:1
Hypertension	115(53.7%)
Hyperlipidaemia	68(31.7)
CAD	102(47.6 %)
COPD	56(26.1%)
Smoking	169(78.9 %)
Renal insufficiency	39(22.3 %)
History of stroke	10(4.6 %)
Diabetes mellitus	30(14.0 %)

CAD, Coronary artery disease; COPD, chronic obstructive pulmonary disease

The mean abdominal aortic diameter was 69 mm (40 -147mm). The proximal cross-clamp position was infrarenal in 178(83.2%) and interrenal/suprarenal in 36(16.8%). All patients had prosthetic polyester grafts implanted. Tube prosthesis was placed in 167(78%) and the remaining 47(22%) had bifurcated reconstructions. The distal target for the bifurcated grafts was iliac arteries in 20(9.3%) and femoral arteries in 27(12.6%).


Aneurysm configuration
180
160
140
120
100
80
60
40
20
0
178
83.2%
36
16.8%
Aneurysm configuration
Infrarenal
Juxtarenal


Distal Target
180
160
140
120
100
80
60
40
20
0
167
78%
47
22%
Distal Target
Aortic Bifurcation
Iliac/Femorals

The perioperative mortality rate was 3.73% (n=8), and major complications occurred in 41(19.1 %) patients (Table II).

Table II. Thirty-day outcomes

Variable	Number (%)
Mortality	8(3.73%)
Major morbidity	41(19.1%)
Renal dysfunction	
Increase in S.Cr >0.5mg/dl	30(14%)
Renal failure *	4 (1.8%)
Respiratory complications	
Respiratory failure #	11 (5.1%)
Re-intubation	7 (3.2%)
Pneumonia	10 (4.6%)
Thromboembolic complications	
Deep vein thrombosis	0 (0)
Pulmonary embolism	0 (0)
Cardiac complications	
Myocardial infarction	4 (1.8%)
Arrhythmia(atrial)	20 (9.3%)
Neurological complications	
TIA/stroke	0 (0)
Spinal cord ischemia	0 (0)
Wound dehiscence	5(2.3%)

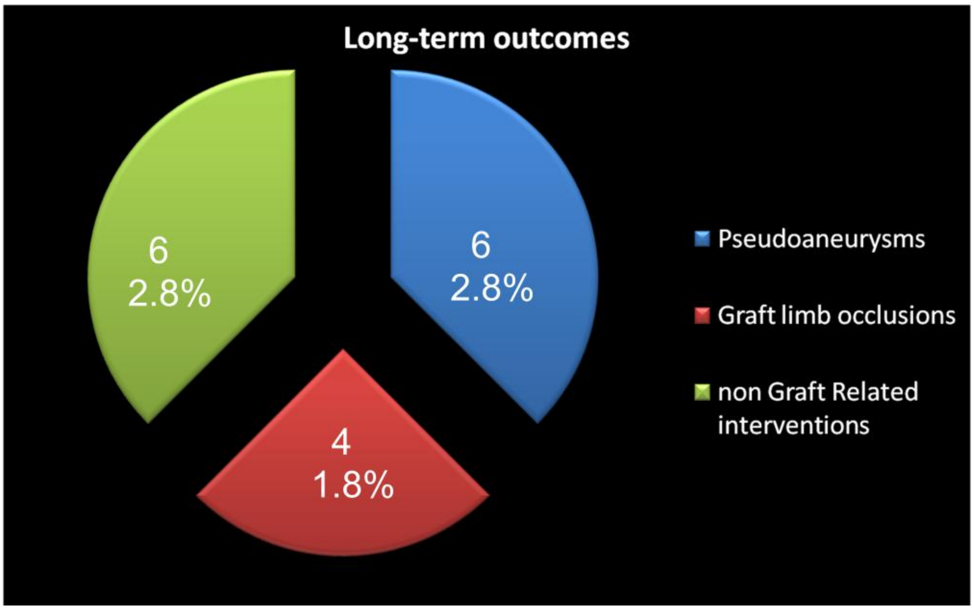
* Requiring haemodialysis

Prolonged ventilator support > 48hrs

Long term complications shown in Table III.

Table III Long term complications

Pseudo aneurysms	6(2.8%)
Graft limb occlusions	4(1.8%)
Graft related reinterventions	8(3.7%)
Non graft related reinterventions.	6(2.8%)



Factors predictive of long term survival with univariate analysis were

1) Age (p=<.001)
2) Coronary artery disease (p=<.001),
3) Renal dysfunction (p=<.001),
4) Size of aneurysm more than 7 cms (p=.027)
5) Reinterventions (p=.005).

Factors predictive of long term survivability with multivariate analysis were

1) Age (p=<.001, HR=5.37, CI for HR-2.74-10.51, HR-hazard ratio, CI-confidence interval),
2) Coronary artery disease (p=.002, HR=3.51, CI for HR-1.60-7.71),
3) Renal dysfunction (p=.002 HR=2.98, CI for HR-1.49-5.93),
4) Reinterventions (p=.045, HR=2.58, CI for HR-1.02-6.53).

   Size of aneurysm was not significant in multivariate analysis.

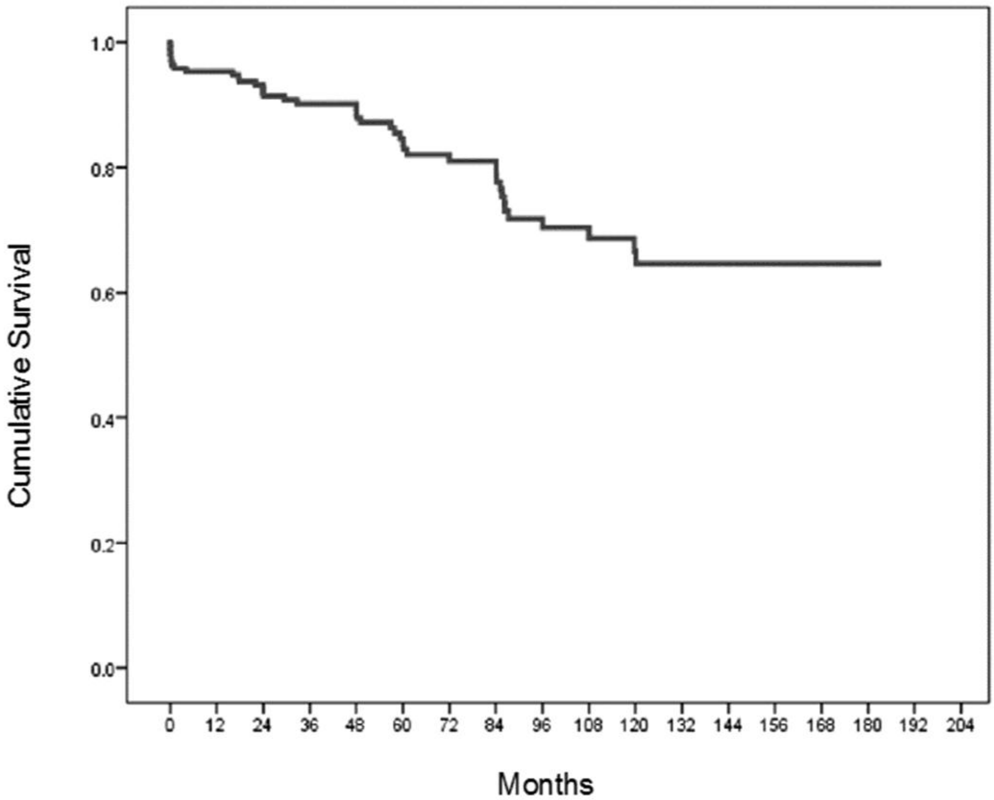
The follow-up period ranged from 1 to 185 months and 172(80.4%) patients remain alive. Negative predictors of long-term survival identified by multivariate model included age, coronary artery disease, renal dysfunction and reinterventions.

2 late aneurysm-related deaths occurred and one patient died from complications related to removal of an infected graft and creating thoraco-bifemoral bypass 6 months after the original operation and the other due to bleeding from left femoral anastomosis elsewhere.

There were 10 graft-related complications which included 6 anastomotic pseudo aneurysms (1 proximal and 5 distal). The proximal pseudo aneurysm underwent Blaisdell procedure and 5 distal ones underwent open operative repair. Of the four graft limb occlusions in the bifurcated grafts, 2 were treated with open thrombectomy and revision of the distal (femoral) anastomosis and 2 were maintained on anticoagulation. Graft-related reintervention was identified by multivariate analysis as significant variable factor for long term survival. 5 and 10 year survival rates were 84.6% and 66.6% as shown in Kaplan–Meier life table analysis.

Histopathology of aneurismal wall was reported as degenerative/atherosclerotic mostly; however in 3 patients below 40 years Takayasu's arteritis was underlying etiopathogenesis.

Kaplan-Meier Life Table analysis



172(80.4%) patients remain alive

5 and 10 year survival rates were 84.6% and 66.6%

DISCUSSION

Abdominal aortic aneurysm is a ubiquitous vascular clinical entity encountered by all populations across the globe. Among all the arterial aneurysms in the body, AAA is commonest and its prevalence is approximately 75%.[12]

SVS and ISCVS, [13] through benchmark studies and trials, have formulated 5.5 cm size as threshold for repair of AAA. Aneurysm measuring 4─5.5 cms is called small AAA that calls for risk factor control and serial follow up for progress in size. The natural history of small aneurysms (4─5.4cm) and the fate of such subjects who harbour these, often silently, are very well elucidated in studies namely UK Small Aneurysm study, [14] Aneurysm Detection and Management Study, [15] natural history studies by Peter Brown from Ontario, Canada and reports by Jack Cronenwett et al.[16, 17] Typically Cronenwett et al mentioned that a third of these patients die from myocardial infarction, stroke, cancer or accident. The remaining two thirds of survivors would require attention to their aneurysm in 1-2 years, meaning thereby small aneurysms would continue to grow in size, and faster as the size increases. Ruptured aortic aneurysm leads to immediate and inevitable death of the patient, if not treated expeditiously. In contradistinction, elective repair of intact aneurysm carries a very high success rate and centres across the globe have achieved 2-3% mortality for open conventional, and less than 1% for endovascular aneurysm repair, ever since Juan C Parodi[18] introduced the revolutionary minimally invasive technique in the early 1990's. Principal determinant for rupture is its size compounded by factors like age, smoking, chronic obstructive pulmonary disease and hypertension.

AAA, even today is by and large incidentally detected and hence rupture chance, operative risk and life expectancy have to be carefully considered before planning and advising treatment. Estimates of the risk for AAA rupture are imprecise because large numbers of patients with AAAs have not been observed without intervention. Studies conducted before the widespread application of surgical repair documented the likelihood of large AAAs to rupture.[19] Data are insufficient to develop an accurate prediction rule for AAA rupture in individual patients, which makes surgical decision making difficult. The estimated risk of rupture is summarized in the following table below.[20]

AAA Diameter	Rupture Risk
(cm)	(%/yr)
<4	0
4-5	0.5-5
5-6	3-15
6-7	10-20
7-8	20-40
>8	30-50.

Operative mortality is the most widely reported of all aneurysm-related statistics in the literature. A review by Blankensteijn and co-workers found that population-based studies reported mortality rates as high as 8% after open AAA repair (prospective) and as a whole are significantly higher than single-centre reports, which averaged 3.8%.[12] A review by Hallin and colleagues found a weighted operative mortality for elective open AAA repair of 5%, [22] consistent with the UKSAT (United Kingdom Small Aneurysm Trial) figure of 5.6%, [23] U.S. hospital discharge data (5.6% in a review of 360,000 repairs), and the Canadian Aneurysm Study (4.8 %).[24] Our study has a 30 day mortality of 3.73 %.

As expected, age is the strongest predictor of life expectancy, which ranges from 18 years for a 60-year-old man to 5 years for an 85-year-old.[25] Survival in patients with AAA, is lower than that in sex and age matched populations without

AAA. In a report from 28 medical centres on 794 patients who survived elective AAA repair, survival rates were 94% at 1 year, 90% at 2 years, 84% at 3 years, 78% at 4 years, and 67% at 5 years.[26] Essentially every subsequent study has confirmed Crawford and colleagues report that cardiac disease and cancer, [27] followed by stroke, [28] pulmonary disease, and renal failure, [29] are, in decreasing order, the principal causes of death in AAA patients. In Batt and associates' series, AAA repair was associated with a reduction in 5-year survival rates from 91% to 72% versus matched controls, [30] Johnston reported that 6-year survival rates decreased from 79.2% to 60.2%.[28]

5 and 10 year survival rates in our study were 84.6% and 66.6% as shown in Kaplan–Meier life table analysis. The cause of death in decreasing order in our study was Myocardial infarction, stroke, malignancy and renal failure.

The principal factors determining long-term survival after identification or initially successful repair of AAAs are not aneurysm related. As would be anticipated, predictors of diminished long-term survival include age at the time of surgery, abnormal renal function, and the presence of cardiovascular disease.[26, 27, and 28]

Factors predictive of long tern survivability with multivariate analysis in our study were, Age (p=<.001, HR=5.37, CI for HR-2.74-10.51, HR-hazard ratio, CI-confidence interval), Coronary artery disease (p=.002, HR=3.51, CI for HR-1.60-7.71), Renal dysfunction (p=.002 HR=2.98, CI for HR-1.49-5.93) and Reinterventions (p=.045, HR=2.58, CI for HR-1.02-6.53).

The perceived excellent durability of open AAA is indeed substantiated in the literature. Hertzer et al[31] reported rare graft-related complications (0.4%) with 5-year follow-up, although only clinically evident (as opposed to computed tomography scan–detected) events were considered. Adam et al[32] reported a low (3.4%) reintervention rate with an average follow-up of 3.4 years, with most being either anastomotic pseudo aneurysms or graft limb thromboses.

The reintervention rate after EVAR has become an increasing problem as results with longer follow-up have become available, thus leading some to question the long-term effectiveness of stent-graft repair.[33]

In contrast to the long-term data associated with open repair, durability studies of EVAR have typically had relatively short surveillance intervals, with most reports averaging less than 24 months of follow-up.[34] Despite this, the reintervention rates have ranged from 8.7% at 12 months (from the EUROSTAR study[34]) to 27% at 18 months. Thus, as intuitively expected, graft-related reintervention is higher in patients undergoing EVAR than in those with open repair.

However, most events leading to secondary intervention after EVAR involved endoleaks, and most of these were managed percutaneously or endovascularly via a groin incision. Despite the minimally invasive nature of reinterventions, frequent admissions for treatment-related complications essentially negate the shorter hospital length of stay enjoyed by EVAR over open repair in the perioperative period.[35]

Graft related reinterventions was 3.73% in our study. There were 10 graft-related complications which included 6 anastomotic pseudo aneurysms (1 proximal and 5 distal). All pseudoaneurysms underwent open operative repair and of the four graft limb occlusions in the bifurcated grafts, 2 were treated with open thrombectomy and revision of the distal (femoral) anastomosis and 2 were maintained on anticoagulation.

CONCLUSIONS

Open repair of AAAs remains a safe and durable option for the management of abdominal aortic aneurysms, with an excellent survival in patients who undergo operation at 70 years of age or younger. Factors predictive of long term survivability with multivariate analysis were age, coronary artery disease, renal dysfunction, and reinterventions. Freedom from graft-related reintervention is superior to that of EVAR with easy surveillance protocol.

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CLASSICAL CASES

Case of Giant Juxta Renal aortic aneurysm with Bi-iliac extension

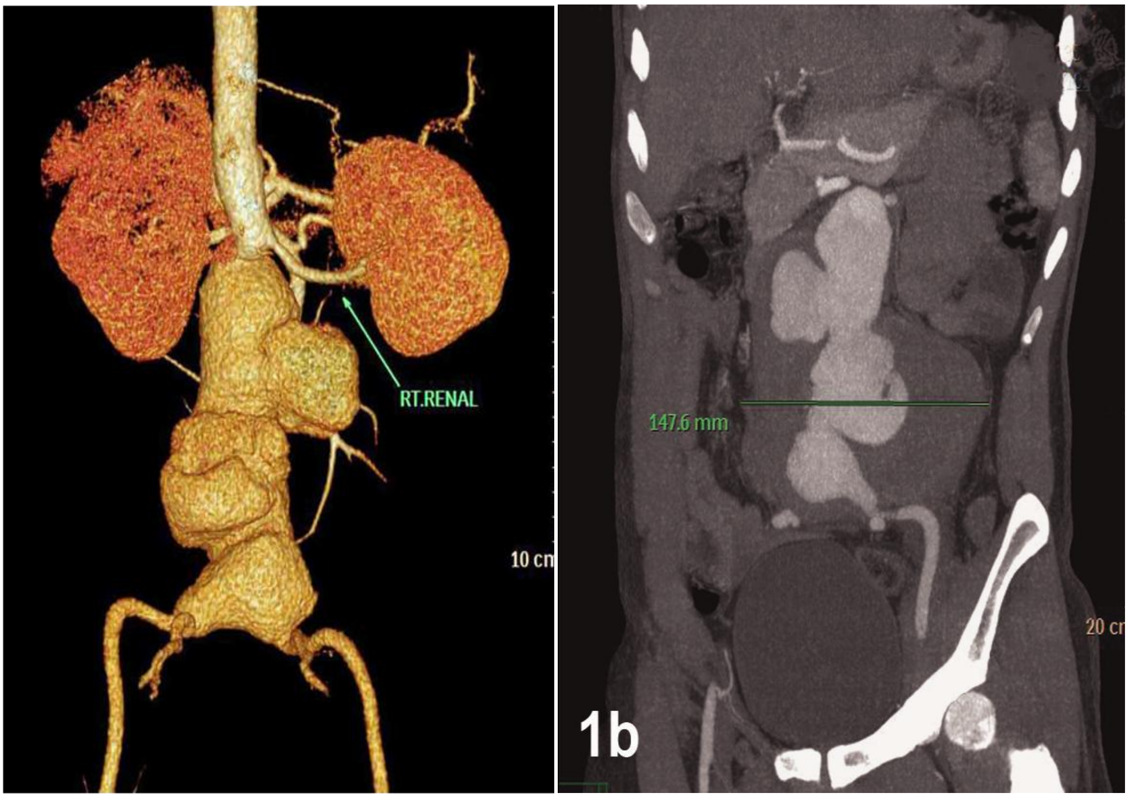
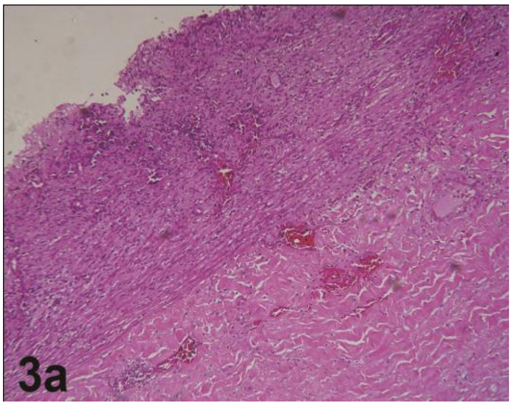


Figure 1a: CT angiogram Volume rendered 3D image showing juxtarenal aortic aneurysm with Bi-iliac extension.

Figure 1b: Coronal section of CT Angiogram of abdomen showing a huge fusi-saccular aneurismal dilatation of infrarenal aorta in flush with left renal artery involving whole of infrarenal aorta with bi-iliac extensions with a maximum diameter of 14.7 cms.

Figure 2a: Per operative image showing aorto biiliac 16X8mm collagen Impregnated Dacron graft. Inferior mesenteric artery carreled to left limb of the Graft.

Figure 2b: Follow up CT angiogram with intact repair status



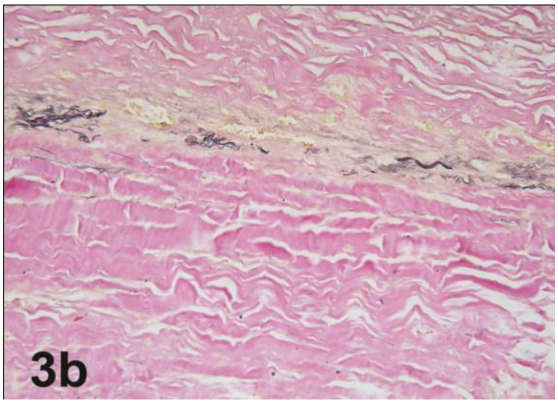
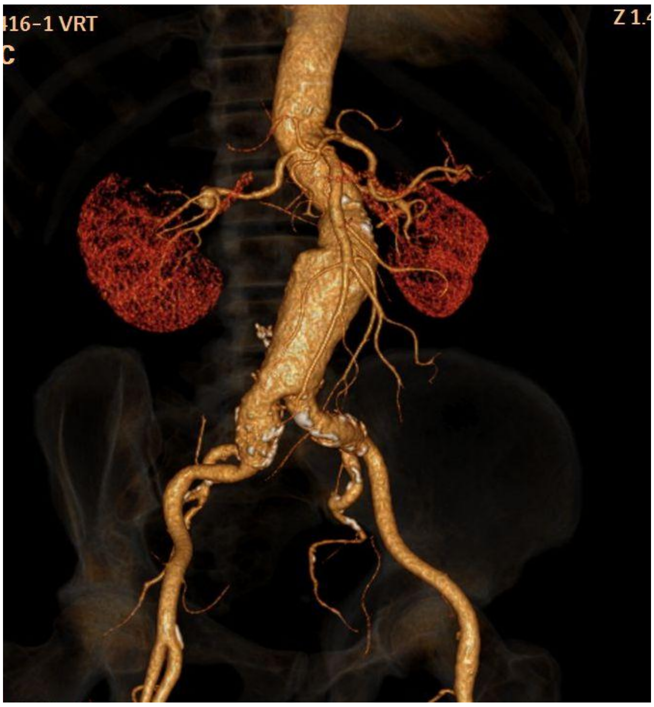


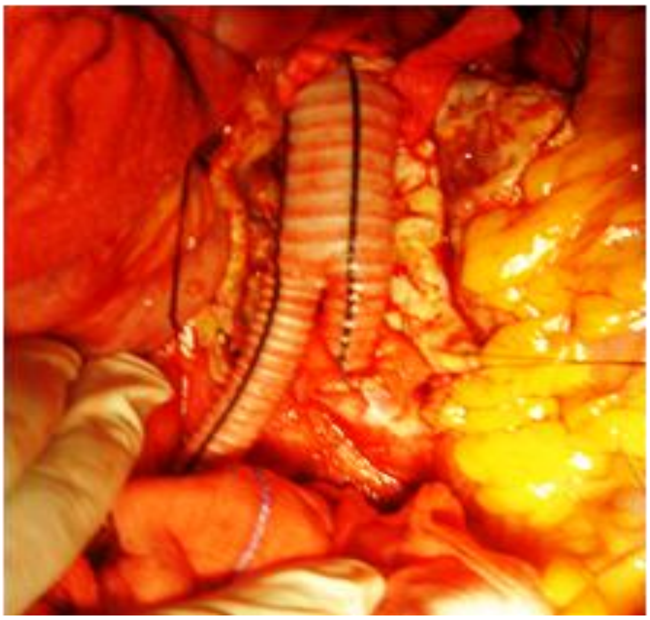
Figure 3a: Low power view with vessel wall showing intense mononuclear inflammation in media and intima and haemorrhage on the thick fibrotic adventia (HE x 100).

Figure 3b: Verhoeff van gieson staining showing the patchy disruption of medial elastic lamina (HE x200)

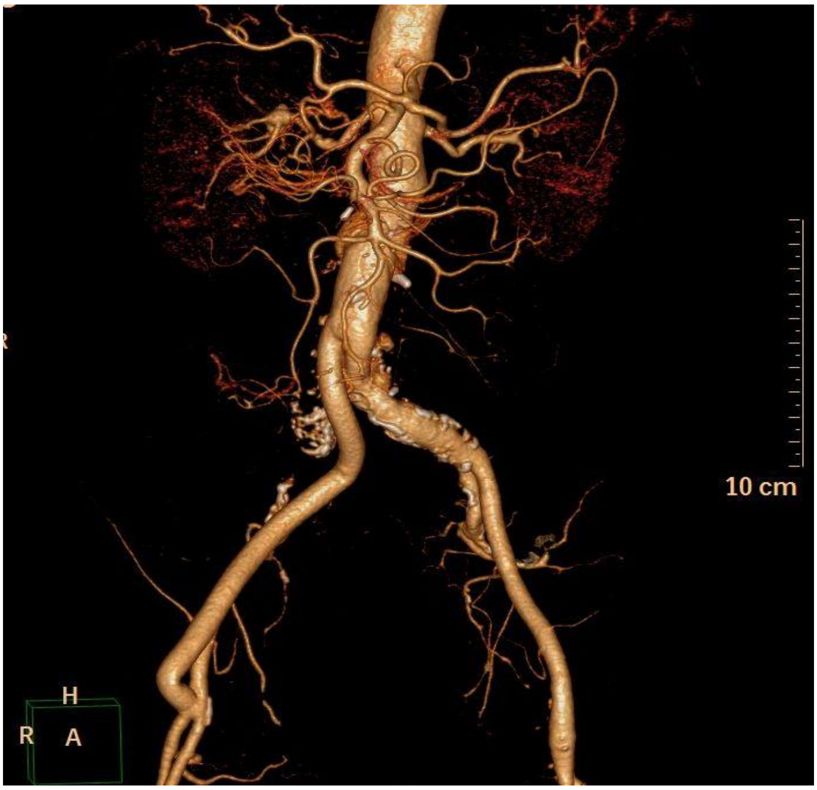
Case of degenerative Infrarenal aortic aneurysm with Bi-iliac extension.



CT angiogram 3D Volume rendered image showing Infrarenal aortic aneurysm with Bi-iliac extension.



Peroperative picture showing repair of aneurysm with bifurcated Dacron graft, aorto right femoral and left iliac bypass



Follow up CT angiogram, volume rendered 3D image showing patent repair status, Aorto-right femoral and left iliac bypass.