EVALUATION OF PREOPERATIVE FUNCTIONAL STATUS USING THE SIX MINUTE WALK TEST AND ITS CORRELATION WITH OUTCOMES FOLLOWING OPEN REPAIR OF ABDOMINAL AORTIC ANEURYSM – A PROSPECTIVE OBSERVATIONAL STUDY

DISSERTATION

Submitted for the partial fulfilment for the requirement of the degree of

MCh in Vascular Surgery

By

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Travancore, an erstwhile province of pre-independent India, was ruled by Maharaja Sree Chitra Tirunal Balarama Varma until the country became independent in 1947. The Government of India took over the province after independence and was incorporated into the state of Kerala.

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

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Dr. Ashutosh Pandey 30/07/2021

Trivandrum

DECLARATION

I, **Dr. Ashutosh Kumar Pandey,** hereby declare that the project in this book was undertaken by me under the supervision of **Dr. Vivek Pillai-** Professor, Dept. of CTVS and **Dr. Shivanesan P.-** Assistant Professor, Division of Vascular Surgery, Dept. of CTVS, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram.

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We hereby declare that; the above statement is true. The candidate, **Ashutosh Kumar Pandey,** has carried out the minimum required work in this project

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INTRODUCTION

Abdominal aortic aneurysm is defined as a pathologic dilatation of aorta, more than 50% of the normal expected diameter (1). While smaller aneurysms can be observed over time, most of the guidelines recommend repair when the diameter reached more than 5.5 cm in the abdominal aorta. (2). Open surgical repair or Endovascular repair are the recommended treatment approaches (3).

The rationale for advocating repair beyond a certain diameter is the risk of rupture which is more with large diameter aneurysms, moreover large diameter at presentation is also predictive of rupture (4).

An aneurysmal rupture is a catastrophe with a mortality of 80% if untreated and about 40% in patients who received treatment in form of surgery or endoluminal repair (5-6). The treatment mode either open or endovascular aim to alleviate symptoms and prevent rupture hence prolonging survival (7)

Open repair of aneurysm has been associated with better long-term outcomes, ease of follow up and lesser reinterventions (8,9). In fit patients open surgical repair in addition to cost effectiveness certainly has a long-term advantage (2). Endovascular repair has been advocated as an alternative approach to open surgical approach, as it offers an early reduction in postoperative mortality and morbidity in comparison to open repair (8,10). Though the long term follow up

studies have shown delayed aneurysm related rupture as well as increased re-intervention in these patients who also need a prolonged follow up (8,9). Considering the pros and cons of these procedures, patient selection becomes a paramount step in decision making especially for open surgery in the management of aortic aneurysm.

Open surgery for abdominal aneurysm, enhances the metabolic requirements of a patient due to the increased requirements for wound healing, ventilation, hemostasis and intraoperative hemodynamics (11,12). In addition, the acid-base fluctuations and stress response to surgery has a significant physiological impact in the peri-operative period (13). A failure to meet the increased requirements in aortic surgery, may lead to cardio-respiratory morbidity and mortality which can be avoided with a risk -stratification guided treatment decision (7).

The incidence of cardiac mortality or a non-fatal myocardial infarction in aortic surgery is more than 5% which is significant (14). A proper preoperative functional assessment is a proven predictor of perioperative morbidity and mortality in aortic surgery (14). A reasonable assumption of functional ability can be devised from the ability to do basic activities for living (15,16).

The commonly used parameter to decide functional ability is Metabolic equivalents (MET) (14). The resting metabolic rate, that is, the amount of oxygen consumed at rest, sitting quietly in a chair is defined as one MET, which

corresponds to approximately 3.5 ml O_2/kg/min (1.2 kcal/min for a 70-kg person) (17). Guidelines from American college of cardiology and American Heart association recommend no further cardiac assessment for patients who can climb a flight of stairs or run a short distance, which corresponds to 4 METS (14). Metabolic equivalent though practiced widely is a subjective method and thus lacks ability to predict outcomes accurately (18,19), necessitating the need of objective testing (7).

The available tests for cardiac function are also limited in predicting cardiorespiratory reserve (7). The static measurement of ejection fraction can't predict cardiorespiratory reserve whereas the dynamic measurements like stress Echocardiography do not assess respiratory function adequately (20,21).

Cardiopulmonary exercise testing (CPET) has emerged as a standard measure of functional capacity, and seems useful in outcome prediction following major surgery (22,23). CPET involves measurement of anaerobic threshold (AT) and peak oxygen consumption thus giving an objective quantification of functional reserve (23,24). Anaerobic threshold is the work rate at which oxygen delivery becomes insufficient and anaerobic substrates are utilized as energy source (7). AT measurement has been utilized in prediction of functional reserve and outcome prediction after aneurysm repair effectively (25).

Well defined AT cut-off values have been devised based on evidence, characterizing the postoperative risks (16). A threshold <11ml O_2/kg/min has

been described to have a higher risk of perioperative events in major non-cardiac surgery (26). Whereas METS are limited by the subjectivity, CPET requires infrastructure and skilled manpower which limits its clinical use (26,27).

The Six-minute walk test (6MWT), has been studied as a feasible, cost effective, simple alternative to exercise testing (28). 6MWT holds more importance in elderly who can develop symptoms at lower values than the proposed exercise capacity (29).

The interpretation of 6MWT is based on the distance covered termed as six-minute walk distance (6MWD), the range of which has been seen to be 400-700 meters in healthy subjects (31). Studies have established a positive correlation between the six-minute walk distance(6MWD) and CPET measurements (26). 6MWT has been well described in pulmonary, major abdominal surgery and Aortic valve replacement (26, 30,31, 32). Limited literature pertains to use of 6MWT as a preoperative predictive marker in aortic aneurysm surgery.

Our center being a tertiary referral Centre, open repair for abdominal aortic aneurysm is routinely performed. This study investigated the correlation of 6 Minute walk test with the post-operative outcomes following open surgery in Abdominal aortic aneurysm. It is among the few studies related to preoperative 6MWT in the subcontinent and the first for patients with aortic aneurysm globally.

AIMS OF STUDY

1- To assess the functional status of patients with Abdominal aortic aneurysm using six-minute walk test

2- To correlate the functional status with perioperative outcomes in patients with Abdominal aortic aneurysm

3- To determine the efficacy of six-minute walk test in predicting cardio-pulmonary reserve.

REVIEW OF LITERATURE

It is more important to know what sort of person has a disease than to know what sort of disease a person has (Hippocrates, 460-370 BC).

Assessment of functional reserve with help of exercise testing has garnered significant attention in the past few decades (7). The majority of patients with aortic aneurysm being elderly and having comorbidities justifies the emphasis on preoperative risk stratification (18). Safety and applicability of exercise testing in patients with Abdominal aortic aneurysm (AAA) has been demonstrated in a study by Myers et al. involving 306 patients with AAA who underwent exercise testing with no serious outcomes reported (33). Carlisle et al in their prospective study from 1999-2006, did exercise testing in 130 patients before AAA repair. The study determined fitness on the basis of CPET and concluded that patients reported unfit on preoperative testing may not benefit from open surgery (34).

The importance of exercise testing has been highlighted by Thompson et al in their prospective study where CPET had a predictive ability for morbidity and all-cause mortality (35). This study emphasizes on use of CPET to standardize the allocation of treatment form (medical vs open surgery or EVAR)

(35). Khan et al in a prospective trial of 30 patients, stated that patients dying after AAA repair did poorly in preoperative exercise test when compared to those who did well (36). They also determined efficacy of simple stair climb test as equivalent to CPET in predicting outcome (37).

Goodyear et. al in the prospective study of 230 patients, stratified risk on basis of anaerobic threshold determined on CPET, patients with AT <11ml/kg/min were not subjected to open repair (7). Classifying the risk based on CPET showed improvement in mid-term survival. This study also highlighted the usefulness of exercise testing in determining the treatment modality and reducing treatment cost (7).

Grant et al. in a two Centre study of 506 patients who underwent preoperative exercise testing identified exercise testing as a predictor of survival irrespective of the type of repair (22). The role of CPET as an important aid to decision making regarding management of AAA was also reiterated. Barakat et al. in their study of 130 patients determined the predictive ability of exercise testing with respect to organ specific mortality (38). Fitness as determined by exercise testing was an important predictor of morbidity and length of stay in open repair of AAA in the study by Prentis et al. involving 185 patients who underwent open and endovascular repair (16).

A low anaerobic threshold and peak oxygen consumption on CPET was predictive of early death following AAA repair as reported by Hartley et al. in

their analysis involving 415 patients (39). Though widely studied, as an objective measure of functional capacity CPET is limited in application as it involves infrastructure and skill not omnipresent (26). Hence arises the need of a simpler reproducible test, which achieves similar objectivity and predictive values as CPET (21).

The Six Minute walk test has been studied and reported as a fair analogue to the Exercise testing, and much simpler to administer (26). The role of 6MWT as a reliable and reproducible measure of exercise capacity was first described by Butland et al. in 1982(40). The safety and acceptability of 6MWT in the assessment of functional capacity in heart failure patients was described by Guyot et al in 1985(41).

The guidelines for conduct of the six-minute walk test were framed by the American thoracic society (ATS) in 2002 (42) followed by a review in 2014(43). Study done by Cathelin et al in patients with heart failure found that in patients with heart failure evaluated for cardiac transplantation, distance ambulated in 6 minutes was a strong predictor of survival (44). A distance less than 300 meters was strongly associated with increased ventilatory and inotropic support. Irfan et al. in their report of 132 heart failure patients also established the effectiveness of 6MWT as a measure of functional capacity (45). They also postulated the association of a walking distance less than 300 meters with poor outcome (45).

The ASSERT trial of Aortic valve replacement gave a significant impetus to 6MWT as it established an objective value along the predictive potential of the test (46). A cut off of 300 meters was established as a predictor of end point below which the incidence of poor outcomes was high (46). In patients with heart failure Rostagno et al. established that 6MWD and Ejection fraction were the only independent markers of mortality where a poor outcome was more in the group with less than 300 meters walk distance (47).

In the Study of Left ventricular dysfunction (SOLVD) registry mortality was higher in patients who walked less than 350 meters with respect to those who walked more than 450 meters (48). In major non cardiac surgery 6MWT was found to be predictive of moderate to severe complications in the multicenter analysis by Ramos et al. (49). Sinclair et al established the correlation of walking distance with anaerobic threshold thus establishing the equivalence of 6MWT to CPET in major non cardiac surgery (26).

Moriello et al in a patient cohort undergoing colon resection did pre and postoperative 6MWT. Their findings supported role of 6MWT as a measure of postoperative recovery. Patients who had intraoperative complications were noted to have a lower 6MWD (50). In a prospective study of 9526 lung transplant patients the 6MWT was found to be strongly predictive of post-transplant survival, an increase in 6MWD was seen to be associated with lower rates of death (51). Micciche et al reported the utility of 6MWT in predicting

cardiopulmonary complications after upper abdominal surgery. Though sample size was small, they devised a cut off distance of 489 meters below which complications were high (52).

Shulman et al assessed the prognostic utility of the 6MWT and other risk assessment tools for 1 year disease free survival (32). The preoperative 6MWT distance walked correlated weakly with 30 days recovery, 12-month disability free survival and cardiovascular outcomes. The 6MWT was found comparable or superior to formal CPET for all outcomes measured (32). Keeratichananont et al evaluated 6MWT in 78 patients posted for major surgery in their prospective cohort study (53). Patient's developing postoperative pulmonary complications (PPC) had a significantly lower preoperative 6MWD compared with patients without PPC. 6MWD of ≤325 meters was a threshold for predicting pulmonary complications with 77% sensitivity and100% specificity, and had a good predictive value for the same (53).

Santos et al in a prospective cohort of patient planned for thoracotomy established 6MWT as a predictor of pulmonary complications (54). Group with pulmonary complications was found to have a significantly lower 6MWD (54). They concluded that 6MWT is an easy, safe, and feasible test for routine preoperative evaluation in pulmonary surgery and may indicate patients with a higher chance of developing postoperative pulmonary complications (54). In healthy patients the range of 6-minute walk distance has been described

between 400-700 metres (31). However, the few published studies have all used different methods, and the predicted distances differ by up to 30% between the studies (55,56).

In aortic aneurysm patients the only study which reports use of 6MWT was done by Hayashi et al (57). They aimed to establish correlation between preoperative self-efficacy and postoperative six-minute walk distance (6MWD) in open AAA surgery. The study concluded that age and preoperative 6 MWD were independent variables of postoperative 6 MWD which was defined as a measure of physical capacity (57).

In an Indian population Ramanathan et al. determined a reference equation for 6MWD based on their study on healthy patients (58). They concluded that 6MWD presents substantial variability in Indian healthy subjects aged 25-80 years. The variability though was adequately predicted by demographic and anthropometric attributes. They also observed that equations devised for western population overestimated the 6MWD measured in Indian subjects (58).

Though literature review showed ample evidence of the utility of CPET in predicting outcomes and risk stratification in aortic aneurysm (7,16,34-37), no studies highlighted the applicability of the 6MWT in the same. Nevertheless, 6MWT has been reported to be efficacious in aortic valve surgeries, heart failure and noncardiac major surgeries (21,30, 49-53). The present literature

supports the role of preoperative objective measurement of functional capacity before elective aneurysm repair. The present study may guide in establishing the subjective measure of fitness below which open repair will have a higher risk of peri-operative adverse outcomes.

METHODS AND METHODOLOGY

A prospective observational study was done in patients operated for Abdominal aortic aneurysm at out centre from June 2019 to June 2021. The functional capacity was assessed by the Six-minute walk test in all patients preoperatively.

Inclusion criteria:

Patients with:

1) Symptomatic Abdominal aortic aneurysm planned for open surgery
2) Asymptomatic abdominal aortic aneurysm > 5.5 cm diameter planned for open surgery

Exclusion criteria:

Patients with:

1) Unstable angina
2) Recent myocardial infarction < 4 weeks
3) Severe claudication
4) Signs of acute expansion, contained rupture or rupture
5) Severe COPD

Conduct of test:

The preoperative evaluation of patients included a detailed history, physical examination, blood tests, chest X-ray, Pulmonary function test electrocardiography and echocardiography. Aneurysm was diagnosed on basis of a Computed tomography (CT) angiogram. In patients with renal dysfunction plain CT or MRI was used for diagnosis and planning. All the patients were informed about the open as well as endovascular options for repair. Patients who consented for open repair were included in the study. Active smokers were encouraged to quit smoking and a 3 weeks gap was maintained from last smoking to surgery.

After admission the patients were encouraged to continue incentive spirometry which was started as soon as plan for open surgery was made. The preoperative medicines for hypertension or diabetes were continued along with addition of bronchodilators as required. The blood pressure, heart rate and glycemic control were monitored preoperatively. Body mass index was calculated after height and weight measurement for all patients. The patients were explained about Six Minute walk test (6MWT) and after proper consent the test was done as per the ATS protocols (42).

The 6MWT was performed indoor in the ward corridor which was having a

length of 40 meters. Markings were made at every 5 meters and resting chairs were available at every 10 meters. The turn-around point was marked with a visible cone. Patient was adequately rested before the test for 10 minutes and a baseline evaluation of blood pressure, heart rate and oxygen saturation were done. A subjective assessment of fatigue or dyspnea was done at baseline.

The patient was verbally instructed about the test. The objective of test which involved walking back and forth in corridor was explained. They were informed about the option of stopping, resting or slowing down as required. The examiner demonstrated the first lap by walking himself along the corridor.

Once the patient started walking timer was started and constant encouragement was given to patient at every lap. In case of the slowing down or resting they were instructed to resume the test as soon as they are comfortable. At any point timer was not stopped, and they were verbally informed 15 seconds before completion. The spot at 6 minutes was marked and patient was escorted back to his bed. The extra distance was marked with a measuring tape and total distance was recorded.

After completion of test, patient was encouraged again, a glass of water was offered. Dyspnoea and fatigue were assessed by Borg scale and measurement of heart rate, blood pressure and oxygen saturation were done. The test was marked incomplete in patients who had any symptoms of chest pain, leg cramps, sweating or severe fatigue. The patients who were not able to complete

the walk were escorted back to bed in a wheelchair, comforted and were asked about what kept them from walking. The 6-minute walk proforma as per guidelines of ATS was recorded accordingly.

Open surgical repair was done in all patients. The surgery was done under General anaesthesia. Incisions in all cases were midline or transverse abdominal. Endoaneurysmorrhaphy was done in all cases with a bifurcated or tubular polyester graft. The patients were shifted to the surgical Intensive care unit immediately after surgery. After weaning off ventilators and inotropic support they were shifted to the ward. Spirometry was started as soon as possible. The patients were encouraged to ambulate once pain free. Oral feeding was started once abdomen was soft and bowel sounds resumed.

Usual practice in our institute is to extubate on same day as soon as patient is fully awake and haemodynamically stable. We defined any duration of ventilation or inotropic support more than one day in postoperative period as significant based on institutional practice.

Post-operative cardiorespiratory complications were reported if patient had any Myocardial ischemia, significant arrythmia or pneumonia requiring prolonged ventilation with culture proven organisms. Additional information was also recorded regarding postoperative bleeding, re-exploration and duration of total stay.

OUTCOME

The primary outcome was to determine whether pre-operative functional capacity determined by 6MWT predicts peri-operative morbidity and mortality.

STATISTICAL ANALYSIS

Analysis was done in this group to explore association between baseline 6MWT and the outcome. The continuous normally distributed values were expressed as means and standard deviation and compared using paired or unpaired t tests as required. Categorical variables were compared with the chi-square test. Fisher's exact test was used when the sampling distribution was uneven.

The median walking distance of our cohort at baseline was 400 meters. Walking performance was classified as low and high keeping 300 meters as cutoff. This cut off was derived from the previous studies in patients posted for aortic surgeries (44-48).

The results of 6MWT and all variables including age, sex, smoking history, body mass index (BMI), diabetes, hypertension, coronary disease, chronic obstructive pulmonary disease were analyzed with respect to cardiopulmonary complications, ICU stay, ventilatory or inotropic support and in hospital stay.

Univariate analysis was done for all the variables. The cut off 6MWD for

cardiorespiratory complications, prolonged ventilatory support and inotropic support was also determined for the cohort.

RESULTS

1-BASELINE CHARACTERISTICS

A total number of 52 patients met the inclusion criteria and were involved in the study. The baseline characters have been described in table 1. The average age of the study group was 65.36 years. Males comprised the majority of patients (n=46, 88%), only 6 patients were females (12%) (Image 1).

The average maximum diameter of aneurysm was 6.98cm. The mean albumin was 4.09 gram/litre, mean serum creatinine was 1.37milligram/decilitre and mean BMI was 24.75 kg/m^2. A significant number of patients (n=49 ,94%) were hypertensive, and had a smoking history (n=41, 79%). Coronary artery disease was present in 28 patients (54%), and only 8 of these patients had underwent percutaneous intervention (PCI) or a coronary bypass. A total of 16 (31%) patients were diagnosed preoperatively with chronic obstructive pulmonary disease (COPD). Diabetes was present in only 7 patients (13%). Of the two patients diagnosed with chronic kidney disease, one patient was on pre-operative maintenance haemodialysis. (Table 1)

Criteria	Mean	
Age	**65.36 years**	
Aneurysm diameter	**6.98 cm**	
BMI	**24.75kg/m2**	
Albumin	**4.09g/dl**	
Serum creatinine	**1.37mg/dl**	
Criteria	Number of patients	Percentage
Sex - **Male** **Female**	 46 6	 88% 12%
Hypertension	49	94%
Diabetes	7	13%
COPD	16	31%
Smoking history	41	79%
CAD **(Post PCI/CABG)**	28 8	54%
CKD	2	3.8%

Table 1 – baseline characteristics of the patients, CAD- coronary artery disease, PCI -percutaneous coronary intervention, CABG – coronary artery bypass grafting, COPD – chronic obstructive pulmonary disease CKD-chronic kidney disease

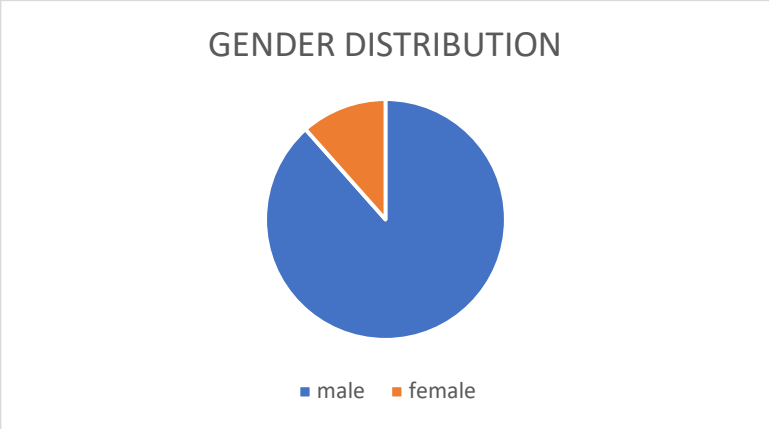

Image 1 – Gender wise distribution of patients

The aneurysm location has been depicted in table 2. Most common type of aneurysm was Infrarenal (IRAAA) (48%), followed by infrarenal alongwith common iliac aneurysms (n=13, 25%) (Image 2). Common iliac aneurysm was repaired in 3 patients. IRAAA repair as a part of staged repair of thoracoabdominal aneurysm was done in one patient.

ANEURYSM LOCATION	Total	
	N	%
Infrarenal (IRAAA)	25	48.1
IRAAA+ CIAA	13	25
JRAAA	7	13.5
Common Iliac	3	5.8
IRAAA +B/L popliteal	1	1.9
IRAAA+CIAA+PROFUNDA	1	1.9
IRAAA+TAAA	1	1.9
JRAAA+CIAA	1	1.9

Total	52	100

Table 2 – Anatomical distribution of aneurysm, IRAAA- infrarenal abdominal aortic aneurysm, CIAA – common iliac artery, TAAA- thoracoabdominal aortic aneurysm, JRAAA- juxta renal aortic aneurysm

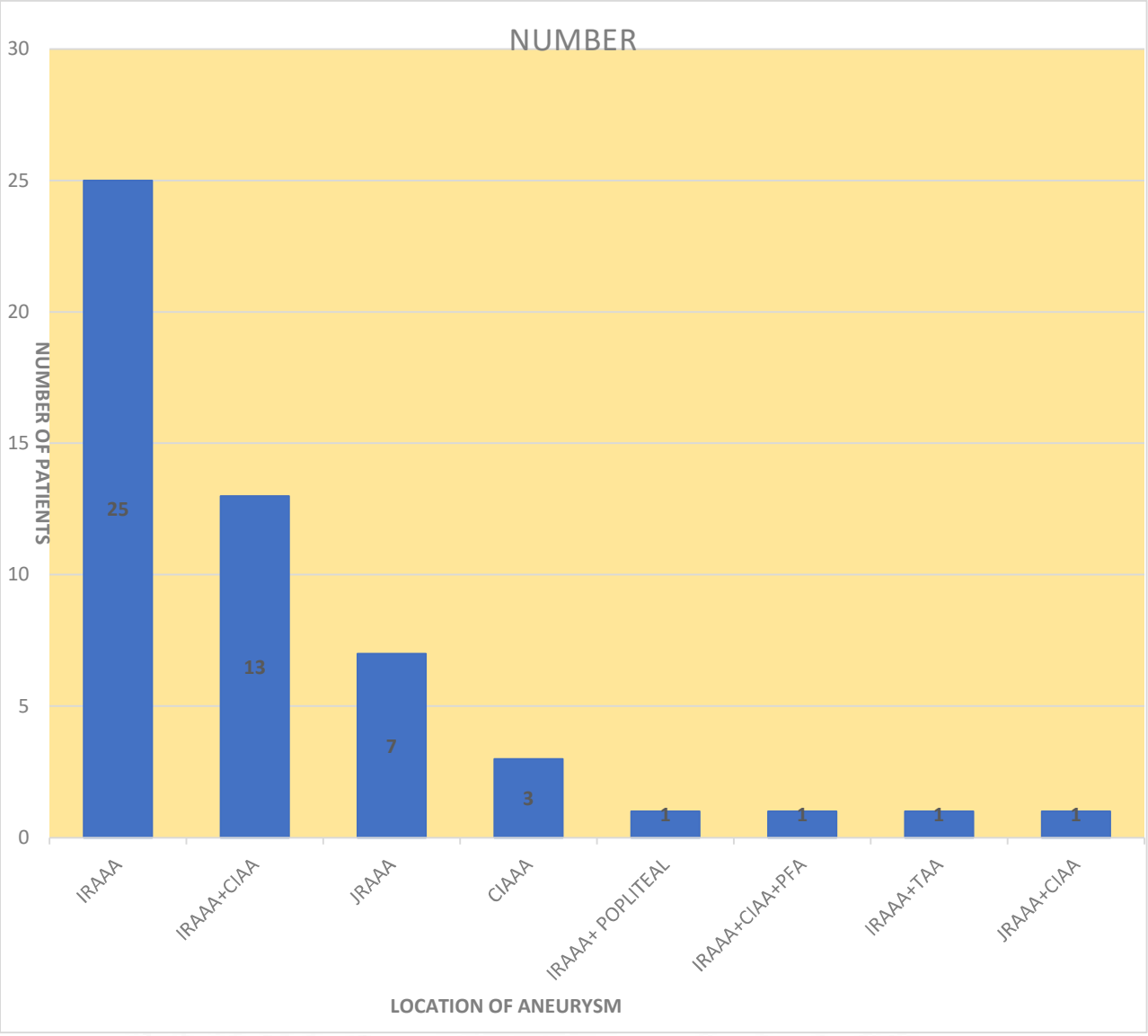

Image 2 – Anatomic distribution of aneurysm, IRAAA- infrarenal abdominal aortic aneurysm, CIAA – common iliac artery, TAAA- thoracoabdominal aortic aneurysm, JRAAA- juxta renal aortic aneurysm

2-SIX MINUTE WALK TEST

2.1 – Test results

The patients falling within the inclusion criteria were made to perform the test in the hospital ward corridor as per protocol. A total of 49 patients were able to complete the test, two patients reported significant fatigue at the start of test and one patient developed leg pain at the start of test. The distance was recorded for the 49 patients. No test related complications were noticed.

The median walk distance was 400 metres, and the average walk distance was 355 metres. The range of distances was from 200 metres to 500 metres(Image-3). The patients were divided in groups walking <300 metres or >300 metres and were analysed with respect to baseline character and outcome. The mean 6MWD of >300 metre group was 415 metres whereas the mean 6MWD of <300 metre group was 216 metres.

The two groups showed no significant difference in age, aneurysmal diameter, albumin, body mass index, creatinine or ejection fraction (table 3). The 6MWT was not significantly affected by gender, or presence of comorbidities (table 4).

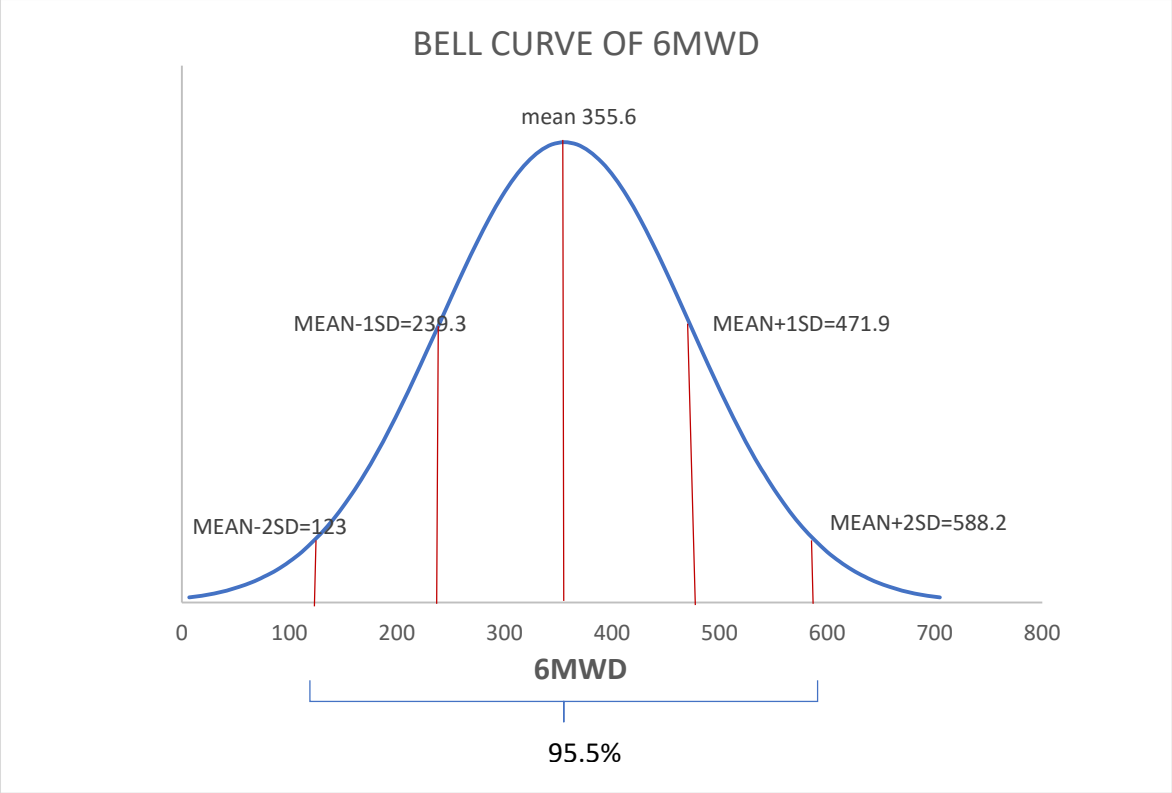

Image 3 – Distribution of the six-minute walk distance (6MWD)

Parameter	6 MWD				P
	≤300 m (n=17)		>300 m (n=35)		
	mean	Sd	mean	Sd	
Age	66.65	9.59	65.00	12.54	0.637
Aneurysm diameter	6.53	1.05	7.20	1.26	0.063
Albumin	4.13	0.37	4.07	0.47	0.674
Creatinine	1.23	0.34	1.44	0.99	0.410
BMI	25.63	4.74	24.32	4.06	0.307
ejection fraction	65.18	6.98	66.54	9.13	0.589

Table 3 – Mean values of baseline variables, in the groups walking <300 metres and > 300 metres. BMI- body mass index

Parameter	6 MWD				p
	≤300 m (n=17)		>300 m (n=35)		
	N	%	N	%	
Sex Male	17	100	29	82.9	0.161
Female	0	0	6	17.1	
DIABETES	3	17.6	4	11.4	0.670
HYPERTENSION	15	88.2	34	97.1	0.246
CAD	5	29.4	23	65.7	0.059
COPD	5	29.4	11	31.4	1.000
COMORBIDITY	3	17.6	9	25.7	0.729
SMOKING	15	88.2	26	74.3	0.304

Table 4- Impact of gender and other comorbidities on the 6MWT, CAD - coronary artery disease, COPD- chronic obstructive pulmonary disease.

2.2 – Clinical Outcomes with respect to 6MWT

Analysis with respect to postoperative outcomes revealed that patients with less than 300 metre walk distance had more ICU stay, inotropic requirement, ventilatory support and cardiopulmonary issues. Patients with a low walking distance had more incidences of pneumonia, bleeding and re-exploration as well.

2.2 (a)- ICU stay

The median ICU stay for the patients was one day. A total of 23 patients had an ICU stay of more than one day. In the group walking <300 metres the ICU stay was more than a day for 15 patients out of the 17 (88%) patients. Most of the patients who had a walk distance of > 300 metres had an ICU stay of one day (n=27, 77%). (Table 5, Image 4)

ICU STAY	6 MWD				Total		χ^2	Df	P
	≤300 m		>300 m						
	N	%	N	%	N	%			
One day	2	11.8	27	77.1	29	55.8	19.8	1	**<0.001**
More than one day	15	88.2	8	22.9	23	44.2			
Total	17	100	35	100	52	100			

Table 5- ICU stay with respect to walk distances

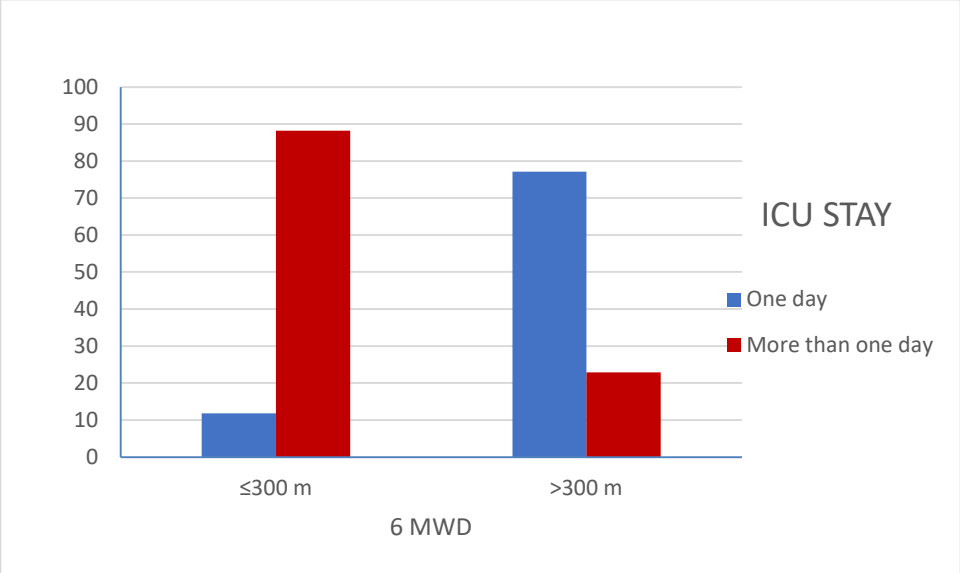

Image 4- graph showing comparison of ICU stay

2.2(b)- Ventilatory and inotropic support

More number of patients in the <300 metres group needed prolonged ventilation and inotropic supports. About half (47%) of the patients in the <300 metres group needed a prolonged ventilatory support as compared to only one patient in the >300 metres group. (p<0.001) (table 6, Image 5)

A significant number (88%) of the patients with walk distance <300 metres had prolonged postoperative inotropic support in intensive care unit (p<0-001). (Table 7, Image 6). The mean duration of inotropic support and ventilatory support was significantly higher in the <300 metres group (p<.001). (Table 8, Image 7)

PROLONGED VENTILATORY SUPPORT	6 MWD				Total		χ^2	df	P
	≤300 m		>300 m						
	N	%	N	%	N	%			
Yes	8	47.1	1	2.9	9	17.3	15.6	1	**<0.001**
No	9	52.9	34	97.1	43	82.7			
Total	17	100	35	100	52	100			

Table 6- Requirement of prolonged ventilatory support

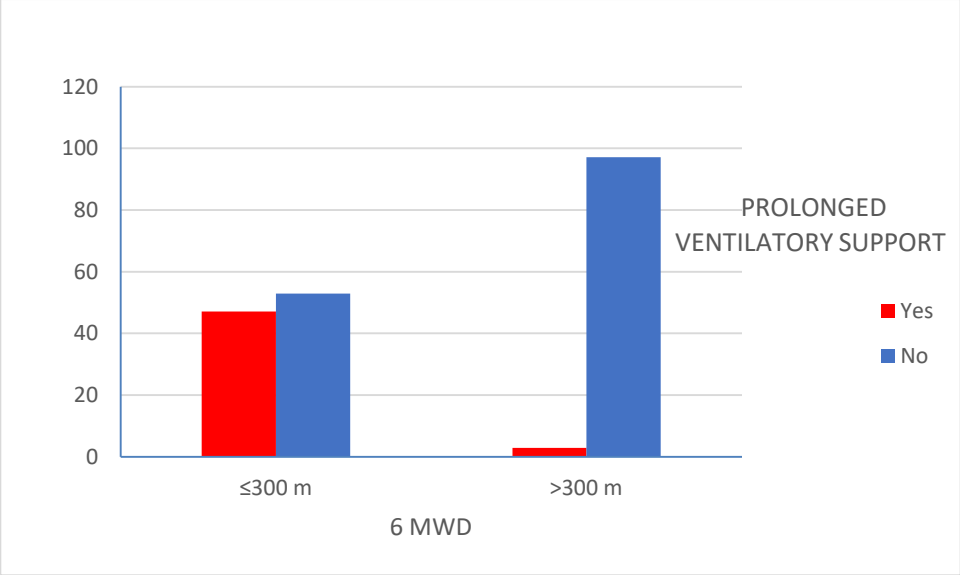

Image 5 – Requirement of prolonged ventilatory support

INOTROPES	6 MWD				Total		χ^2	df	P
	≤300 m		>300 m						
	N	%	N	%	N	%			
Yes	15	88.2	3	8.6	18	34.6	32.1	1	**<0.001**
No	2	11.8	32	91.4	34	65.4			
Total	17	100	35	100	52	100			

Table 7 – inotropic support with respect to 6MWT '

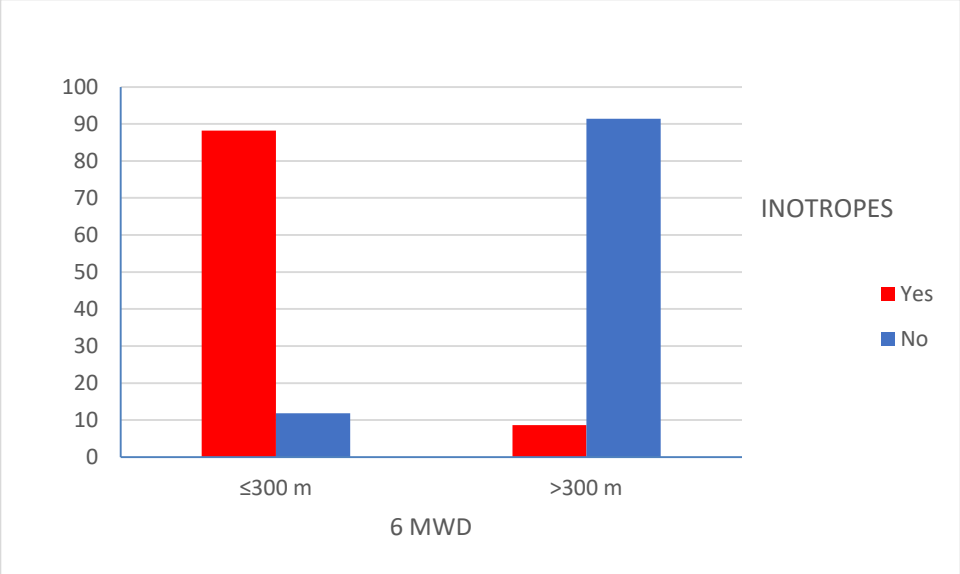

Image 6- inotropic support with respect to 6MWT

Parameters	6 MWD				P
	≤300 m (n=17)		>300 m (n=35)		
	mean	Sd	mean	Sd	
Ventilatory support (hours)	51.47	66.88	6.89	9.77	**<0.001**
Inotropes (duration in hours)	52.82	59.01	3.83	6.85	**<0.001**

Table 8- Mean duration of inotropic/ventilatory support

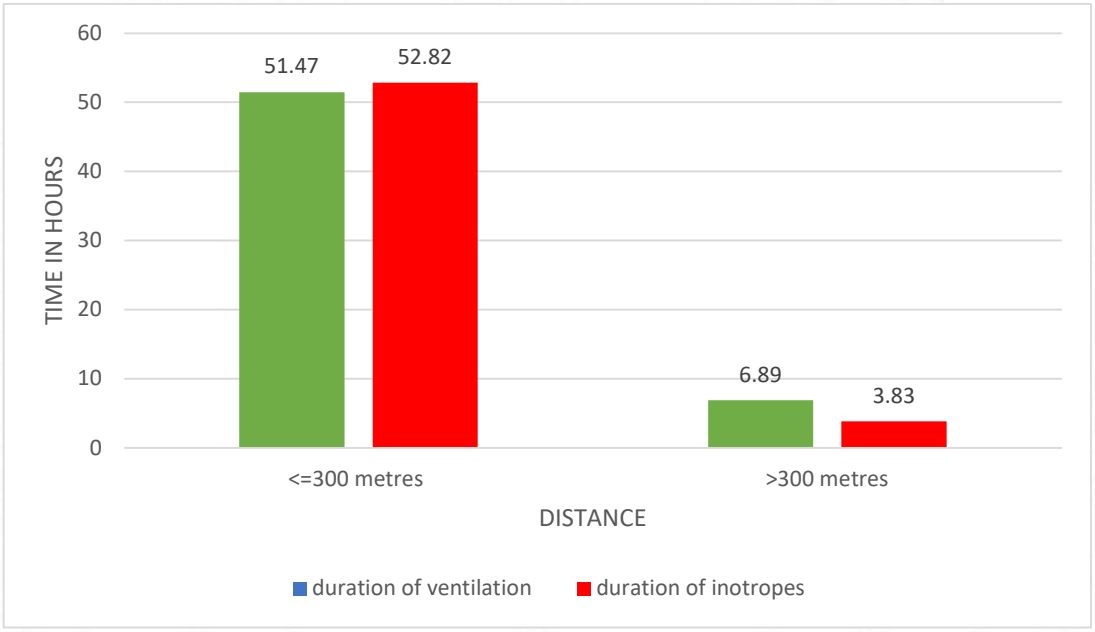

Image 7- mean duration of ventilatory /inotropic support

2.2 (c)- Cardio-pulmonary Issues

Cardio-pulmonary issues were defined as occurrence of cardiac events (arrythmia/MI) and or pneumonia. Cardio-pulmonary issues were present in 11 patient (21.2%). Of the patients with 6MWD <300 metres 8 (47%) had peri-operative cardio-pulmonary issues. (Table 9, Image 8)

In the < 300 metres group (n=17), 3 patients had arrythmia in the form of atrial fibrillation in the perioperative period, arrythmia was controlled in all 3 cases with antiarrhythmics. Myocardial infarction as defined by increase in cardiac biomarkers with ECG changes and or symptoms, was witnessed in two patients, medical management was done in both cases. The incidence of significant arrythmia or myocardial infarct was more in <300 metres group (29% vs 2,9%, p=.005). Pneumonia was diagnosed on basis of clinical features, chest radiology supported by organism growth is respiratory tract secretions. Management was done with culture-based antibiotics or empirical upgradation of antibiotics. Chest physiotherapy and incentive spirometry was started early in post-operative period. In the study group 7 patients (13.4%) had postoperative pneumonia. The incidence of pneumonia was also noted to be higher in the <300 metres group (29% vs 5.7 %, p=0.019). (Table 10,11; Image 9,10).

CARDIAC-PULMONARY ISSUES	6 MWD				Total		χ^2	df	P
	≤300 m		>300 m						
	N	%	N	%	N	%			
Yes	8	47.1	3	8.6	11	21.2	10.2	1	**0.001**
No	9	52.9	32	91.4	41	78.8			
Total	17	100	35	100	52	100			

Table 9- cardiopulmonary issues with respect to 6MWT

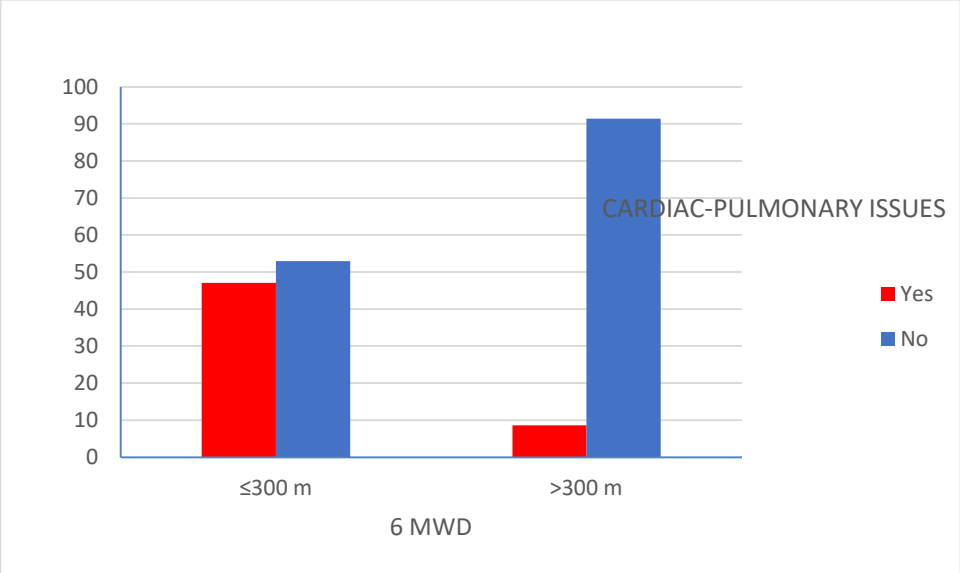

Image 8 – cardiopulmonary issues with respect to 6MWT

CARDIAC EVENTS	6 MWD				Total		χ^2	df	P
	≤300 m		>300 m						
	N	%	N	%	N	%			
Yes	5	29.4	1	2.9	6	11.5	7.91	1	**0.005**
No	12	70.6	34	97.1	46	88.5			
Total	17	100	35	100	52	100			

Table 10-Incidence of cardiac events with respect to 6MWT

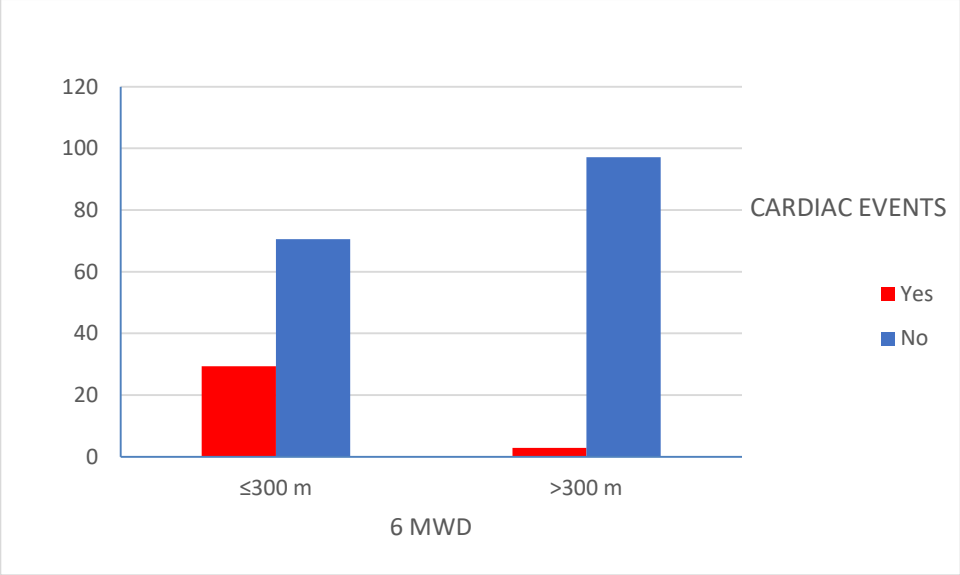

Image 9 -Incidence of cardiac events with respect to 6MWT

PNEUMONIA	6 MWD				Total		χ^2	df	p
	≤300 m		>300 m						
	N	%	N	%	N	%			
Yes	5	29.4	2	5.7	7	13.5	5.52	1	**0.019**
No	12	70.6	33	94.3	45	86.5			
Total	17	100	35	100	52	100			

Table 11- Incidence of pneumonia with respect to 6MWT

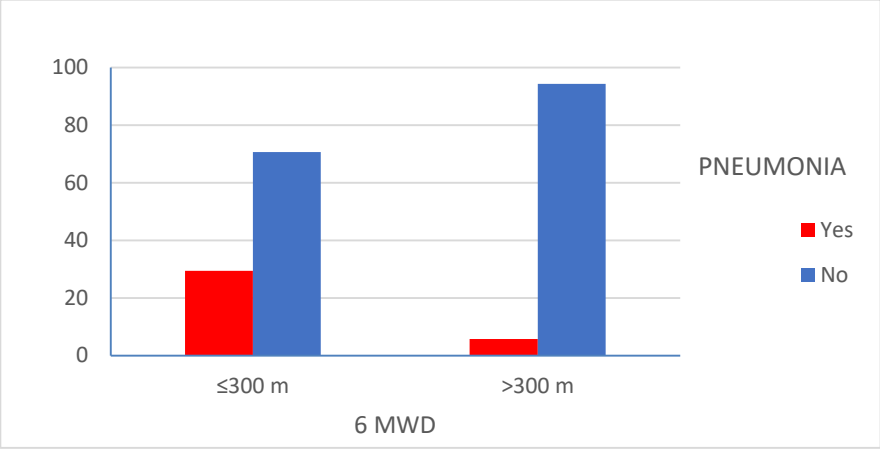

Image 10- Incidence of pneumonia with respect to 6MWT

2.2(e)- Mean duration of In-hospital stay

The mean duration of stay for the study cohort was 9.11 days. Patients with a low walk distance were noted to have more duration of stay. The average duration of stay was 10.59 in the <300 metres group as compared to 8.40 in the >300 metres group. (p<=0.01). (Table 12, Image 11)

6 MWD	N	Duration of stay in days		p
		Mean	Sd	
≤300	17	10.59	4.17	**0.010**
>300	35	8.40	1.75	

Table 12- duration of in-hospital stay

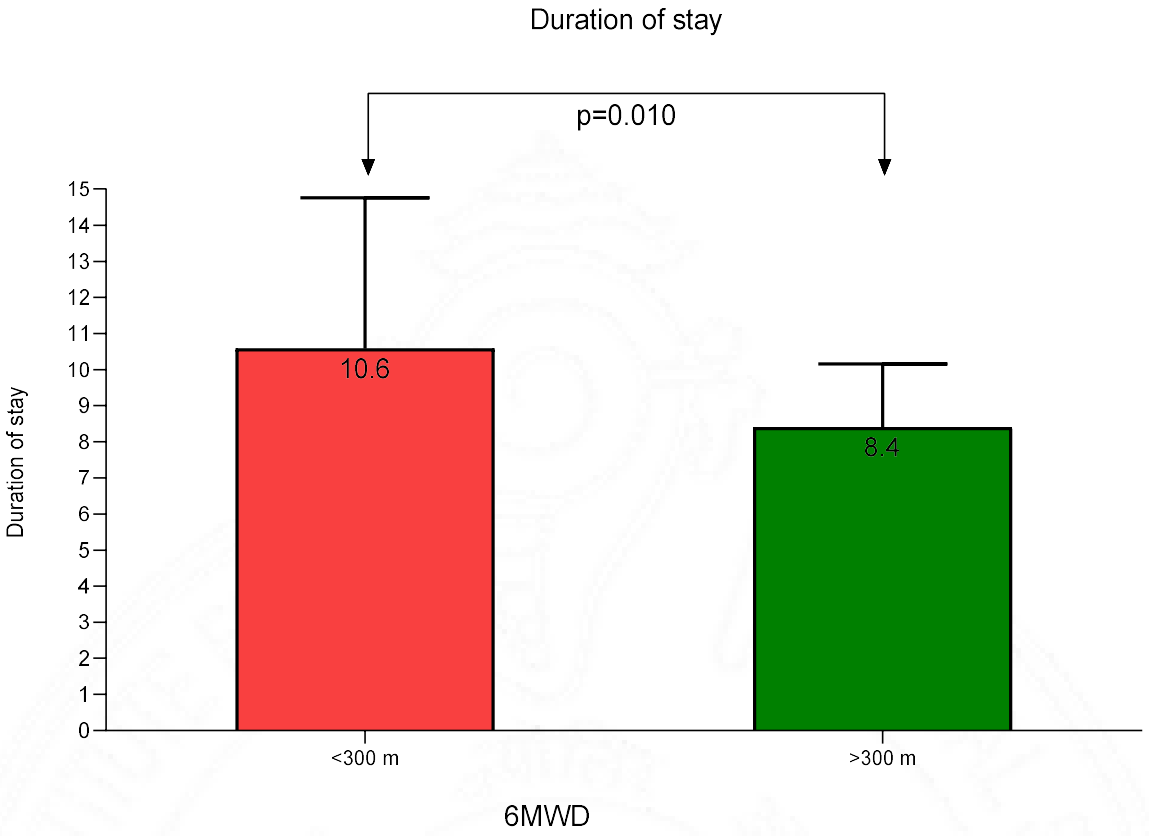

Image 11 – Duration of in-hospital stay

2.2(f)- Final outcome

There were 3 mortalities in the study group(5.8%) .Two of the patients had cardiac events whereas one mortality was attributed to pulmonary complications further compounded by renal failure .

The 6MWD showed a significant correlation with the in-hospital mortality. All the patients who died had a 6MWD of <300 metres**.** (Table 13, Image 12)

OUTCOME	6 MWD				Total		Fisher's Exact test p
	≤300 m		>300 m				
	N	%	N	%	N	%	
Death	3	17.6	0	0	3	5.8	**0.031**
Discharged	14	82.4	35	100	49	94.2	
Total	17	100	35	100	52	100	

Table 13 – final outcome at 30 days

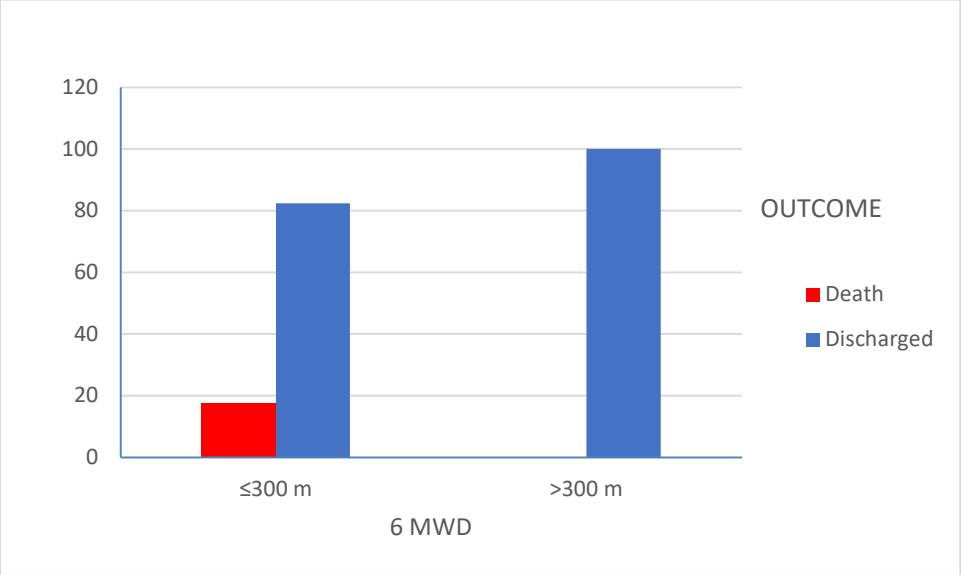

Image 12 – final outcome at 30 days

2.3- Assessment of cut-off values for 6MWD with respect to outcome

The mean 6MWD was calculated for patients having cardio-pulmonary complications and requiring increased ventilatory or inotropic support. Cardiopulmonary issues were predicted at a mean walk distance of 298 metres though this was not statistically significant(p=.099). A distance of

241 metres or less was predictive of increased inotropic support(p=0.003). Increased ventilatory support was seen in patients with a mean walk distance less than 247 metres(p=<0.001).(Table 14, Image 13-14)

The 6MWD values for adverse outcomes were lower than 300 metres in all cases, thus justifying the risk classification based on a 300 metres threshold.

PARAMETERS		N	6 MWD (m)		P
			Mean	Sd	
CARDIAC-PULMONARY ISSUES	Yes	11	298.2	71.0	0.099
	No	41	364.4	124.8	
INOTROPES	Yes	18	241.7	128.1	**0.000**
	No	34	407.9	56.8	
PROLONGED VENTILATORY SUPPORT	Yes	9	247.8	116.4	**0.003**
	No	43	371.9	107.8	

Table 14 – Mean walk distance in subgroup of patients with cardio-pulmonary issues, prolonged inotropic and ventilatory support

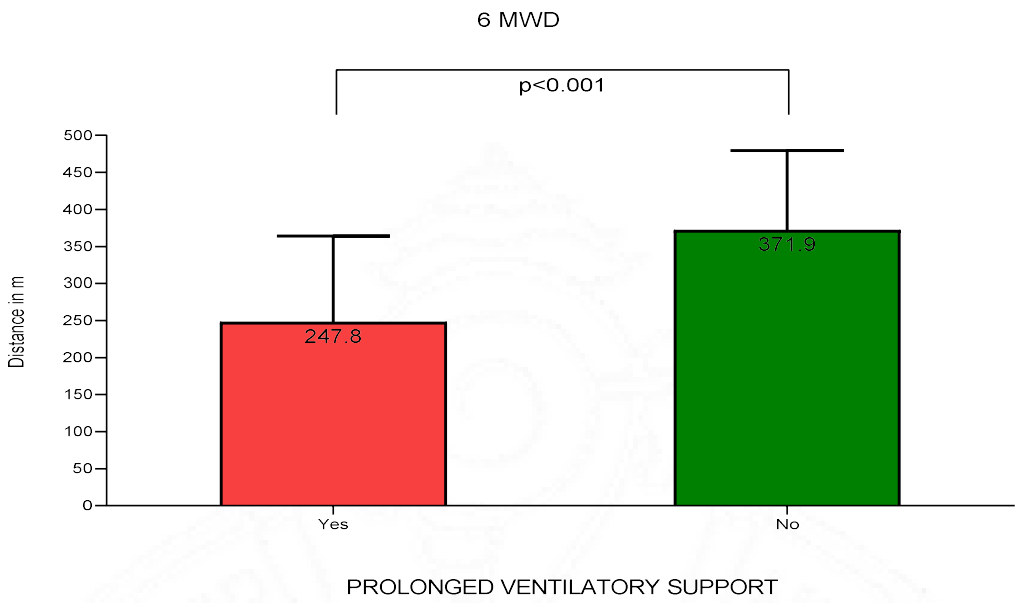

Image 13 - Mean walk distance in subgroup of patients requiring prolonged ventilatory support

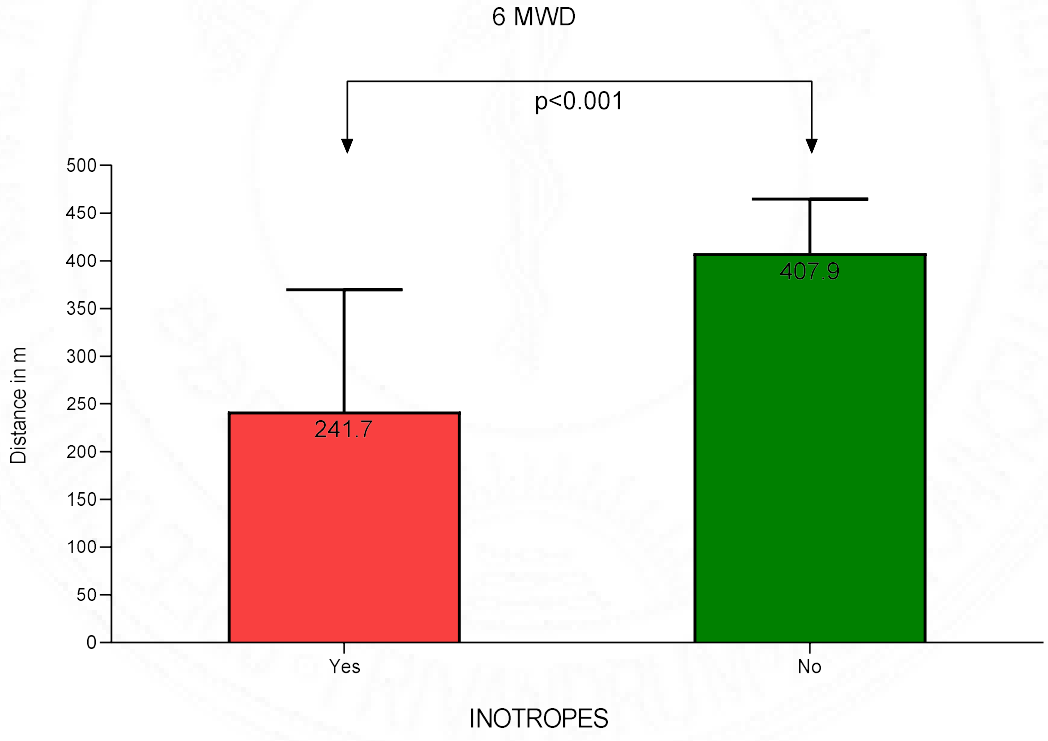

Image 14- Mean walk distance in subgroup of patients requiring inotropic support

2.4 – Other factors affecting outcome

An analysis of the baseline morbidities including Diabetes, hypertension, coronary disease, COPD and smoking history was a done with respect to peri-operative outcomes. None of the factors were significant with respect to the occurrence of cardiopulmonary events, inotropic dependence or ventilatory support. (Table 15)

	CARDIAC-PULMONARY ISSUES				Total		χ^2	df	p
	Yes (n=11)		No(n=41)						
	N	%	n	%	n	%			
DIABETES	2	18.2	5	12.2	7	13.5	0.3	1	0.605
HYPERTENSION	9	81.8	40	97.6	49	94.2	4.0	1	0.047
CAD	4	36.4	24	58.5	28	53.8	1.7	1	0.190
COPD	2	18.2	14	34.1	16	30.8	1.0	1	0.308
SMOKING	9	81.8	32	78	41	78.8	0.1	1	0.786
	PROLONGED VENTILATORY SUPPORT				**Total**		χ^2	**df**	**p**
	Yes (n=9)		No(n=43)						
	N	%	N	%	n	%			
DIABETES	2	22.2	5	11.6	7	13.5	0.7	1	0.397
HYPERTENSION	6	66.7	43	100	49	94.2	15.2	1	0.000
CAD	2	22.2	26	60.5	28	53.8	4.4	1	0.056
COPD	1	11.1	15	34.9	16	30.8	2.0	1	0.160
SMOKING	6	66.7	35	81.4	41	78.8	1.0	1	0.325

	INOTROPES				Total		χ^2	df	p
	Yes (n=18)		No(n=34)						
	N	%	n	%	n	%			
DIABETES	4	22.2	3	8.8	7	13.5	1.8	1	0.178
HYPERTENSION	16	88.9	33	97.1	49	94.2	1.4	1	0.229
CAD	6	33.3	22	64.7	28	53.8	4.7	1	0.051
COPD	3	16.7	13	38.2	16	30.8	2.6	1	0.109
SMOKING	16	88.9	25	73.5	41	78.8	1.7	1	0.197

Table 15- Analysis of baseline factors with respect to, cardiopulmonary complications, ventilatory support or inotropic support.

DISCUSSION

This study demonstrated the safety and feasibility of Six Minute walk test (6MWT) in patients with abdominal aortic aneurysm. We established that patients with a walk distance <300 metres had more adverse events in the perioperative period when compared to the group with >300 metres 6MWD. There have been no previous studies on the preoperative 6MWT as a predictor of clinical outcomes in patients undergoing abdominal aortic aneurysm repair.

The open repair in AAA aims to prolong the overall survival of patients. The patients with AAA usually have significant comorbidities, which may be life threatening in the perioperative period (34). Further the surgery and perioperative period are physiologically challenging and poor outcomes are not uncommon in patients with impaired functional capacity (7, 59).

The assessment of ability to perform activity of daily living is a valid predictor of functional status (60). The metabolic equivalents (METS) have been recommended as a validated measure for preoperative assessment of functional status (14). Subjective assessment of functional capacity with METS score in patients with AAA lacks predictive accuracy and is susceptible to confounding (18,19).

Physical fitness is not well predicted by static measures of cardiac function such as ejection fraction (21). Dynamic testing in forms of stress echo or

electrocardiogram are limited to cardiac status and are not indicative of respiratory function (7). Exercise testing combines the assessment of cardiac and respiratory function with objective values to predict functional status (24). The safety and feasibility of exercise testing in AAA is well established (7,33,34). Preoperative objective assessment of functional capacity in aortic aneurysm has been shown to improve peri-operative outcomes and reduce hospital costs (7). Exercise testing in AAA has been demonstrated to be a predictor of survival, morbidity and length of stay (16,22,39).

Though reliable, exercise testing is limited to few centres owed to the requirement of specialised infrastructure and skilled manpower (26,28). The 6MWT has been validated as an effective surrogate to exercise testing (26). The distance walked in six minutes correlates well with the peak oxygen consumption on CPET which is an identified predictor of clinical outcomes (26,44,47). The 6MWT offers a cost effective, reproducible, reliable and efficient measure of functional capacity (26-28).

Our study establishes the role of 6MWT as a measure of pre-operative fitness in AAA repair. Ideally the preoperative stratification of patients based on 6MWD involves the use of reference values in order to compare the achieved value with expected values (54). The standard reference equations for healthy patients

involve height, age, sex and weight of the patient (55). But most of the studies deriving these reference equations are based on western population (53,58).

In an India based study the mean walking distance in healthy population was 495 metres (sd-83.85, range 294-691metres) (58). Moreover, the reference equation derived from healthy western population would overestimate the 6MWD in our cohort as majority of the patients with AAA had restrictive comorbidities.

We classified the patients on basis of walk distance <300 metres and >300 metres. This cut-off was derived from the previous studies on aortic valve surgeries which showed increased incidence of peri-operative morbidity and mortality in the <300 metres group (44-48).

The study involved patients who were either symptomatic for AAA or had a maximum diameter of more than 5.5 centimetres. The patients included in this study were explained about both the treatment options namely open repair and endovascular repair. The patients with low 6MWD or issues during 6MWD were further counselled about the risk of perioperative adverse events. The decision to opt for open surgery in most of the patients was driven by financial constraints.

This study for the first time evaluated preoperative functional status using 6MWT in AAA patients. The study identified the risk groups for morbidity and mortality and also predicted cut off with respect to perioperative issues. Preoperative assessment with 6MWT involves almost no extra cost and its of

certain value in centres with limited infrastructure. The findings from this study can serve to establish 6MWT as a risk stratification tool for AAA, and help in allocation of treatment strategy.

The limitations of this study were, a small sample size hence bias cannot be ruled out for establishing 6MWT as a strong predictor for perioperative complications. Secondly there was no reference equation or standard cut-off values for 6MWD for the study population. In addition, a comparative analysis with other risk models (CPET or MET) could have aided in validating the efficacy. Also, though the 6MWT was predictive of adverse peri-operative outcomes, the use of a single dichotomous variable for outcome analysis limits the findings.

Since the safety is established, future studies can be done with larger number of patients. Post-operative 6MWT can be compared with baseline and also serve as a marker of recovery. A long term follow up will help decide role of 6MWT in predicting survival.

CONCLUSION

Six-minute walk test can be safely performed in patients with Abdominal aortic aneurysm. A low walking distance correlates directly with increased peri-operative morbidity and length of hospital stay. A distance of <300 metres in patients with Aortic aneurysm is predictive of peri-operative morbidity and mortality. The patients with a walk distance less than 300 metres should be optimised or advised endovascular repair as first option in managing aortic aneurysm.

Further studies aiming at comparison of pre-operative and postoperative 6MWT can additionally identify role of 6MWT as marker of recovery. Studies in a larger group of patients and long term follow up will further help in establishing the predictive efficacy of 6MWT.

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ABBREVIATIONS

1. MET- Metabolic equivalents
2. CPET- Cardiopulmonary exercise testing
3. AT- Anaerobic threshold
4. 6MWT- Six-minute walk test
5. 6MWD- Six-minute walk distance
6. AAA- Abdominal aortic aneurysm
7. EVAR- Endovascular aneurysm repair
8. ATS- American thoracic society
9. PPC- Post-operative pulmonary complications
10. CT- Computerised tomography
11. MRI- Magnetic resonance imaging
12. BMI-Body mass index
13. ICU- Intensive care unit
14. COPD- chronic obstructive pulmonary disease
15. CAD- coronary artery disease
16. IRAAA- Infrarenal abdominal aortic aneurysm
17. CIAA- Common iliac artery aneurysm
18. JRAAA- Juxta-renal abdominal aortic aneurysm
19. TAAA- Thoracoabdominal aortic aneurysm

ANNEXURES

PLAGIARISM CERTIFICATE

Curiginal

Document Information

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TAC/IEC CERTIFICATE

18

Technical Advisory Committee (Clinical Studies)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2019/913 **Date:14.05.2019**

Project title: EVALUATION OF PREOPERATIVE FUNCTIONAL STATUS USING THE SIX-MINUTE WALK TEST AND ITS CORRELATION WITH OUTCOMES FOLLOWING OPEN REPAIR OF ABDOMINAL AORTIC ANEURYSM: A PROSPECTIVE OBSERVATIONAL STUDY

Principal Investigator:
Dr. Ashutosh Kumar Pandey, Senior Resident, Division of Vascular Surgery, Department of CVTS, SCTIMST Degree: MBBS, MS
Co-Principal Investigator(s)
Dr.P .Shivanesan, Assistant Professor, Division of Vascular Surgery, Department of CVTS, SCTIMST Degree- MS ,Mch (Vascular surgery
Dr. Vivek Pillai, Additional Professor Department of CTVS, SCTIMST Degree – MS , MCh CTVS

Members who participated in the TAC meeting on 30/04/2019

Dr. Rupa Sreedhar (Chairperson)
Dr. Sankara Sarma P
Dr. Prasantakumar Dash
Dr. Sylaja. P.N
Dr. Krishna Kumar K
Dr. Varghese T. Panicker
Dr. Sanjay G
Dr. Syam K
Dr. K. Shivakumar (Member Secretary)

Dr. Sanjay G, Dr. Sylaja. P.N, Dr. Syam K, Dr. Rupa Sreedhar, Dr. Prasantakumar Dash and Dr. Krishna Kumar K stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#,905, 906. 908, 909, 910, 911, 918).

Risk Classification of the project (Minimum/ Moderate/ High): Minimum

Requirement of DSMB: Yes

Recommended members of DSMB:

Dr. Varghese T Panicker, Additional Professor, Department of CVTS, SCTIMST
Dr. Bineesh Radhakrishnan, Assistant Professor, Department of CVTS, SCTIMST
Dr. Prasantakumar Dash, Professor, Department of Anaesthesiology, SCTIMST
Dr. Subin Sukesan, Associate Professor, Department of Anaesthesiology, SCTIMST
Dr. Saravana Babu, Assistant Professor, Department of Anaesthesiology, SCTIMST

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

Appendix-1

1. Its a study to evaluate functional status in the pre op period.
2. Both inclusion and exclusion critera are well choosen
3. As we are looking at the post op outcome include the following in the patient information proforma
   a. Specific cardiac event parameters b. Duration of surgery c. Perioperative analgesia used d. Intraoperative blood product

   Answer: The points are of concern and have been appropriately incorporated in revised Performa.

4. Can a patient with pain due to abdominal aneurysm be made to walk without risk of aneurysm rupture?

   Answer: The risk of aneurysm growth or rupture is nil. Various studies have subjected aneurysm patients to moderate intensity exercise testing for pre-operative stratification and no adverse effects reported yet. Moreover the 6 minute walk test is submaximal exercise testing so comparatively safer than exercise testing. The patients who fall in high risk for rupture on exertion are those with a contained rupture and acute expansion which we have excluded from study.

5 Please include DSMB
Answer: DSMB form has been uploaded in revised submission

IEC- SCTIMST/IEC/1417/AUGUST-2019

PATIENT RECORD PROFORMA

PROFORMA No:

AGE/SEX-

ANTHROPOMETRY

Height-

Weight-

BMI-

RISK FACTORS:

Hypertension

Diabetes

Coronary Artery disease

Peripheral Arterial disease

COPD

Dyslipidemia

Smoker

INDICATION FOR SURGERY

6 MINUTE WALK TEST RECORDING

Blood pressure:___ /___

Heart Rate

Dyspnea_____(Borg scale)

Fatigue_____(Borg scale)

SpO2___ %___%

Stopped or paused before 6 minutes if Yes, reason: _____

Other symptoms at end of exercise: angina dizziness hip, leg, or calf pain

Number of laps: (40 meters)

final partial lap:___ meters

Total distance walked in 6 minutes:_____meters- 6-minute walk distance 6MWD

PREOPERATIVE IMAGING

Chest X Ray

CT Angio

Maximum diameter

Iliac vessels

Femoral vessels

ECHO scan

Coronary Angiogram

PREOPERATIVE WORK UP

Hemoglobin

Albumin

Serum Creatinine

LFT

ESR/CRP

OPERATIVE DETAILS

Duration of surgery

Blood loss

Cardiac event

Hypotension

Units of blood transfused

IMMEDIATE POST OP

Analgesia-

Cardiac Event

MI-

Arrythmia-

CHF-

Bleeding

Hematoma

Re exploration

Uncontrolled Hypertension/hypotension

Post-operative inotropic supports

Duration of ventilation

Reason if prolonged> 24 hrs

Post-operative pneumonia -

Sepsis-

Positive cultures-

ICU stay

Total duration of hospital stay

Follow Up-

1 week

Cardiac event-

Respiratory event-

Documentation of complaints-

Wound healing-

Vitals-

PR-

BP-

RR-

Weight-

1 month

Cardiac event-

Respiratory event-

Documentation of complaints-

Wound healing-

Vitals-

PR-

BP-

RR-

Mortality -

Post-operative day-

Cause-

MASTER CHART

s. no	NAME	H.NO	AGE	SEX	ANEURYSM LOCATION	ANEURYSM DIAMETER(cms)	DIABETES
1	PANKAJAKSHAN	191001	57	m	IRAAA	7	NO
2	KOCHAPPAN	216585	80	M	CIAA	6	NO
3	NARAYAN P	252244	75	M	IRAAA+CIAA+PROFUNDA	7	NO
4	BABU M	281762	44	M	CIAA	4	NO
5	DIVAKARN N	351122	74	M	IRAAA+CIAA	8	YES
6	ANANTHU MA	369100	21	M	IRAAA+CIAA	7	NO
7	KRISHNA K P	391650	74	M	IRAAA	6	NO
8	SUKUMARA PILLAI	392009	67	M	JRAAA	7	NO
9	SULAIMAN AM	405278	57	M	IRAAA+ Left CIAAA	7	NO
10	MOHANAN NAIR	410489	66	M	IRAAA+ Left CIAAA	7	YES
11	MATHEW VARGHESE	426063	69	M	IRAAA	6	NO
12	POCKER	450127	78	M	IRAAA+ CIAA	7	NO
13	S. BAGHEL	453780	54	F	IRAAA	8	NO
14	KUNJUMON	454157	60	M	IRAAA	6	NO
15	THAMPI	459272	76	M	IRAAA	7	NO
16	GOMATHY	461656	75	F	IRAAA	7	NO
17	PAPPACHAN	462511	73	M	IRAAA	8	NO
18	KUMARAN KT	463503	62	M	IRAAA	6	NO
19	**KARUNAK PILLAI**	464200	76	M	IRAAA+TAA	7	NO
20	RASHEED	465487	61	M	IRAAA	7	NO
21	MUSTAFA KUNJU	467245	71	M	IRAAA	8	NO
22	MOHANAN M	467564	66	M	IRAAA+CIAAA	8	NO
23	CHANCHAL RAJ	468353	47	F	IRAAA	4	NO
24	gopi k	468739	63	M	IRAAA+B/LPOPLITEAL AA	7	NO
25	SREEDHARAN NADAR	468850	72	M	IRAAA	7	NO
26	ABUBAKER KP	469112	67	M	IRAAA+CIAA	6	YES
27	SHEEJA A	469849	43	F	IRAAA+ LEFT CIAA	7	NO
28	SIVARAJAN	470094	58	M	IRAAA	5	NO
29	MURALEEDHARAN N	470745	70	M	IRAAA	10	NO
30	KARUNAKARAN K	471370	78	M	JRAAA	8	NO
31	SHAMSHUDDEEN M	471472	70	M	IRAAA	6	NO
32	MATHAI	471476	68	M	IRAAA+CIAAA	7	NO

s. no	NAME	H.NO	AGE	SEX	ANEURYSM LOCATION	ANEURYSM DIAMETER(cms)	DIABETES
33	J NADAR	471860	79	M	JRAAA+CIA	7.5	NO
34	BALACHANDRAN	472686	56	M	JRAAA	7.5	NO
35	HAMSA KUNJU	475034	78	M	JRAAA	10	NO
36	THANGAVAL	476804	61	M	JRAAA	10	NO
37	VELAYUDHAN	478577	63	M	JRAAA	6	YES
38	SEBASTIAN	478626	73	M	IRAAA	6	NO
39	SKARIA	481893	67	M	JRAAA	7	NO
40	LICY VINIOLA	481967	53	F	IRAAA	7	NO
41	STEPHENSOS	482993	76	M	IRAAA	8	NO
42	GANGADHARAN	483135	66	M	IRAAA	8	YES
43	SUNDERESAN	487627	68	M	IRAAA+LEFT CIAA	6	NO
44	THANKAYYAN	488974	82	M	IRAAA	8	NO
45	MAHILAMANI	489036	61	F	IRAAA	7	YES
46	ROY CHERIAN	491532	60	M	IRAAA	6	NO
47	KURUVILLA	495075	70	M	IRAAA+CIAA	5	NO
48	SAJI KUMAR	495867	51	M	CIAA	8	NO
49	RAJAGOPALAN	496665	84	M	IRAAA	7	NO
50	KAMARUDEEN	496963	65	M	IRAAA+CIAAA	6	NO
51	RAJAN NK	497971	58	M	IRAAA	7	YES
52	KALIDHAS	498462	56	M	IRAAA+ Left CIAAA	8	NO

s. no	NAME	HYPERTENSION	CAD	COPD	COMORBIDITY	SMOKING	albumin	creatinine	BMI
1	PANKAJAKSHAN	YES	YES	YES		YES	4.3	1.69	26.7
2	KOCHAPPAN	YES	YES(PCI)	NO		YES	4.6	1.44	26.4
3	NARAYAN P	NO	NO	NO		NO	4.3	1.02	27.7
4	BABU M	NO	NO	NO		NO	4.4	0.92	35.2
5	DIVAKARN N	YES	NO	YES		YES	4.1	1.26	35.6
6	ANANTHU MA	YES	NO	NO	CKD 5	NO	3.7	6.69	23.1
7	KRISHNA K P	YES	YES(CABG)	NO		YES	4.8	1.15	24.7
8	SUKUMARA PILLAI	YES	YES(CABG)	NO		YES	3.9	1.49	20.1
9	SULAIMAN AM	YES	YES	NO		YES	3.9	1.03	20.1
10	MOHANAN NAIR	YES	YES	YES		YES	3.8	1.01	20.9
11	MATHEW VARGHESE	YES	CAD(PCI)	YES		YES	3.9	1.3	28
12	POCKER	YES	CAD(PCI)	YES		YES	4	1.1	18.6
13	S. BAGHEL	YES	NO	NO	TAKAYASU ARTERIT	NO	3.6	1.08	30.2
14	KUNJUMON	YES	YES	YES	CVA	YES	4.2	1.25	20.9
15	THAMPI	YES	CAD	YES		YES	3.7	1.08	23.5
16	GOMATHY	YES	CAD	NO		NO	3.7	1.07	16.2
17	PAPPACHAN	YES	CAD	NO		NO	4.4	1.11	26.1
18	KUMARAN KT	YES	CAD(PCI)	YES		YES	4.5	1.03	25.7
19	**KARUNAK PILLAI**	YES	CAD	NO		YES	4.2	1.36	26
20	RASHEED	YES	NO	YES		YES	2.8	1.54	17.3
21	MUSTAFA KUNJU	YES	YES	NO	MM/HYPOTHYROID	YES	3.6	1.83	29.2
22	MOHANAN M	YES	YES	YES		YES	3.8	1.33	18.4
23	CHANCHAL RAJ	YES	NO	NO		NO	4.6	0.98	26.3
24	gopi k	YES	NO	NO	CVA	YES	3.5	1.33	22.4
25	SREEDHARAN NADAR	YES	NO	YES		YES	4.5	1.48	30.5
26	ABUBAKER KP	YES	CAD	NO	CVA	YES	4	1.19	22.9
27	SHEEJA A	YES	NO	NO	TAKAYASU ARTERIT	NO	3.6	0.49	26.1
28	SIVARAJAN	YES	YES	YES		YES	4.3	0.91	23.4
29	MURALEEDHARAN N	YES	YES	NO		YES	4	1.1	20.1
30	KARUNAKARAN K	YES	CAD	NO		YES	3.4	1.68	19.6
31	SHAMSHUDDEEN M	YES	CAD	NO		YES	3.5	1.04	27.4
32	MATHAI	YES	CAD	NO		YES	4.3	1.5	25.1

s. no	NAME	HYPERTENSION	CAD	COPD	COMORBIDITY	SMOKING	albumin	creatinine	BMI
33	J NADAR	YES	CAD	NO		YES	3.8	0.95	22.4
34	BALACHANDRAN	YES	CAD	NO		YES	4.7	1.08	25.2
35	HAMSA KUNJU	YES	CAD(CABG	YES		YES	4.3	1.36	24.9
36	THANGAVAL	YES	CAD	NO		YES	4.2	2.11	23.4
37	VELAYUDHAN	YES	NO	NO		YES	4.3	1.01	25.4
38	SEBASTIAN	YES	NO	NO		YES	4	2.29	21.9
39	SKARIA	YES	NO	NO		YES	3.4	1.12	21.8
40	LICY VINIOLA	YES	NO	NO		NO	3.8	0.83	22.4
41	STEPHENSOS	YES	CAD	YES		YES	4	1.89	27.1
42	GANGADHARAN	YES	NO	NO		YES	4.4	1.04	24.9
43	SUNDERESAN	YES	NO	YES		YES	4.5	1.15	28.4
44	THANKAYYAN	YES	NO	YES		YES	4.4	1.16	20.4
45	MAHILAMANI	YES	NO	NO	CA BREAST	NO	4.1	0.7	21.9
46	ROY CHERIAN	YES	NO	NO		YES	3.8	1.66	20.7
47	KURUVILLA	YES	NO	NO	CVA	YES	4.2	1.43	30.5
48	SAJI KUMAR	NO	NO	NO	DLP	NO	5.3	1.6	29.1
49	RAJAGOPALAN	YES	NO	NO	CKD	YES	4.7	2.3	24.3
50	KAMARUDEEN	YES	CAD(PCI)	NO		YES	4.5	1.39	26.1
51	RAJAN NK	YES	NO	NO		YES	4.4	0.89	27.6
52	KALIDHAS	YES	NO	NO	DVT	YES	4.1	0.98	34.2
							4.0923077	1.373461538	24.75
							0.4373925	0.837320387	4.288311

s. no	NAME	ISSUES 6MWT	6MWD in metres	ICU STAY (days)	VENTILATORY SUPPORT(hrs)
1	PANKAJAKSHAN	NO	400	2	24
2	KOCHAPPAN		450	2	6
3	NARAYAN P	LL PAIN	280	2	48
4	BABU M	LL PAIN	250	2	48
5	DIVAKARN N	-	0	4	97
6	ANANTHU MA	NO	400	1	6
7	KRISHNA K P	NO	450	1	6
8	SUKUMARA PILLAI	NO	500	1	6
9	SULAIMAN AM	NO	450	2	8
10	MOHANAN NAIR	NO	500	1	6
11	MATHEW VARGHESE	NO	400	1	0
12	POCKER	NO	380	1	0
13	S. BAGHEL	NO	400	1	0
14	KUNJUMON	NO	300	1	0
15	THAMPI	DYSPNOEA	250	1	0
16	GOMATHY	NO	350	1	24
17	PAPPACHAN	NO	500	1	24
18	KUMARAN KT	NO	370	1	0
19	**KARUNAK PILLAI**	NO	**400**	1	24
20	RASHEED	NO	350	1	0
21	MUSTAFA KUNJU	NO	350	1	0
22	MOHANAN M	NO	400	1	0
23	CHANCHAL RAJ	NO	450	1	4
24	gopi k	LL ULCER	0	2	24
25	SREEDHARAN NADAR	NO	400	1	0
26	ABUBAKER KP	NO	400	1	24
27	SHEEJA A	NO	400	1	0
28	SIVARAJAN	NO	400	1	0
29	MURALEEDHARAN N	NO	500	1	0
30	KARUNAKARAN K	NO	370	2	0
31	SHAMSHUDDEEN M	NO	350	1	0
32	MATHAI	NO	470	1	6

s. no	NAME	ISSUES 6MWT	6MWD in metres	ICU STAY (days)	VENTILATORY SUPPORT(hrs)
33	J NADAR	FATIGUE	250	2	48
34	BALACHANDRAN	FATIGUE	200	10	6
35	HAMSA KUNJU	NO	400	2	24
36	THANGAVAL	NO	350	1	0
37	VELAYUDHAN	NO	300	3	48
38	SEBASTIAN	FATIGUE	200	11	264
39	SKARIA	LL PAIN	250	7	144
40	LICY VINIOLA	NO	400	1	0
41	STEPHENSOS	NO	400	2	0
42	GANGADHARAN	NO	450	1	0
43	SUNDERESAN	NO	300	6	4
44	THANKAYYAN	FATIGUE	250	4	0
45	MAHILAMANI	NO	450	1	24
46	ROY CHERIAN	ACUTE PAIN	0	2	24
47	KURUVILLA	NO	300	3	24
48	SAJI KUMAR	NO	450	2	24
49	RAJAGOPALAN	NO	400	3	0
50	KAMARUDEEN	NO	250	6	72
51	RAJAN NK	NO	300	2	24
52	KALIDHAS	LL PAIN	450	1	1

s. no	NAME	PROLONGED VENTILATORY SUPPORT	INOTROPES (hrs)	prolonged inotropes
1	PANKAJAKSHAN	NO	NO	NO
2	KOCHAPPAN	NO	24	YES
3	NARAYAN P	YES	48	YES
4	BABU M	YES	48	YES
5	DIVAKARN N	YES	96	YES
6	ANANTHU MA	NO	6	NO
7	KRISHNA K P	NO	0	NO
8	SUKUMARA PILLAI	NO	6	NO
9	SULAIMAN AM	NO	8	NO
10	MOHANAN NAIR	NO	8	NO
11	MATHEW VARGHESE	NO	0	NO
12	POCKER	NO	0	NO
13	S. BAGHEL	NO	4	NO
14	KUNJUMON	NO	4	NO
15	THAMPI	NO	6	NO
16	GOMATHY	NO	6	NO
17	PAPPACHAN	NO	2	NO
18	KUMARAN KT	NO	0	NO
19	**KARUNAK PILLAI**	NO	6	NO
20	RASHEED	NO	0	NO
21	MUSTAFA KUNJU	NO	0	NO
22	MOHANAN M	NO	0	NO
23	CHANCHAL RAJ	NO	0	NO
24	gopi k	NO	24	YES
25	SREEDHARAN NADAR	NO	0	NO
26	ABUBAKER KP	NO	24	YES
27	SHEEJA A	NO	0	NO
28	SIVARAJAN	NO	0	NO
29	MURALEEDHARAN N	NO	0	NO
30	KARUNAKARAN K	NO	24	YES
31	SHAMSHUDDEEN M	N0	0	NO
32	MATHAI	N0	4	NO

s. no	NAME	PROLONGED VENTILATORY SUPPORT	INOTROPES (hrs)	prolonged inotropes
33	J NADAR	YES	48	YES
34	BALACHANDRAN	NO	72	YES
35	HAMSA KUNJU	NO	6	NO
36	THANGAVAL	NO	0	NO
37	VELAYUDHAN	YES	48	YES
38	SEBASTIAN	YES	264	YES
39	SKARIA	YES	48	YES
40	LICY VINIOLA	NO	0	NO
41	STEPHENSOS	NO	0	NO
42	GANGADHARAN	NO	0	NO
43	SUNDERESAN	NO	24	YES
44	THANKAYYAN	NO	24	YES
45	MAHILAMANI	NO	0	NO
46	ROY CHERIAN	NO	48	YES
47	KURUVILLA	NO	24	YES
48	SAJI KUMAR	YES	0	NO
49	RAJAGOPALAN	NO	0	NO
50	KAMARUDEEN	YES	48	YES
51	RAJAN NK	NO	24	YES
52	KALIDHAS	NO	6	NO

s. no	NAME	CARDIAC-PULMONARY ISSUES	CARDIAC EVENTS	PNEUMONIA	SSI	BLEEDING	REEXPLORATION
1	PANKAJAKSHAN	NO	NO	NO	NO	NO	NO
2	KOCHAPPAN	NO	N0	NO	NO	NO	NO
3	NARAYAN P	YES	ARRYTHMIA	NO	NO	YES	YES
4	BABU M	YES	NO	NO	NO	YES	YES
5	DIVAKARN N	NO	NO	NO	NO	NO	YES
6	ANANTHU MA	NO	NO	NO	NO	NO	NO
7	KRISHNA K P	NO	NO	NO	NO	NO	NO
8	SUKUMARA PILLAI	NO	NO	NO	NO	NO	NO
9	SULAIMAN AM	NO	NO	NO	NO	NO	NO
10	MOHANAN NAIR	NO	N	NO	NO	NO	NO
11	MATHEW VARGHESE	YES	NO	YES	NO	NO	NO
12	POCKER	NO	NO	NO	YES	NO	NO
13	S. BAGHEL	NO	NO	NO	NO	NO	NO
14	KUNJUMON	NO	NO	NO	NO	NO	NO
15	THAMPI	NO	NO	NO	NO	NO	NO
16	GOMATHY	NO	NO	NO	NO	NO	NO
17	PAPPACHAN	NO	NO	NO	NO	NO	NO
18	KUMARAN KT	NO	NO	NO	NO	NO	NO
19	**KARUNAK PILLAI**	NO	NO	NO	NO	NO	NO
20	RASHEED	NO	N	N	NO	NO	NO
21	MUSTAFA KUNJU	NO	NO	N	NO	NO	NO
22	MOHANAN M	NO	NO	NO	NO	NO	NO
23	CHANCHAL RAJ	NO	NO	NO	NO	NO	NO
24	gopi k	NO	NO	NO	NO	NO	NO
25	SREEDHARAN NADAR	NO	NO	NO	NO	NO	NO
26	ABUBAKER KP	NO	NO	NO	NO	NO	NO
27	SHEEJA A	NO	NO	NO	NO	NO	NO
28	SIVARAJAN	NO	NO	NO	NO	NO	NO
29	MURALEEDHARAN N	NO	NO	NO	NO	NO	NO
30	KARUNAKARAN K	NO	N0	N0	NO	NO	NO
31	SHAMSHUDDEEN M	NO	N0	N0	N0	N0	N0
32	MATHAI	NO	N0	N0	N0	N0	N0

s. no	NAME	CARDIAC-PULMONARY ISSUES	CARDIAC EVENTS	PNEUMONIA	SSI	BLEEDING	REEXPLORATION
33	J NADAR	YES	ARRYTHMIA	NO	NO	NO	NO
34	BALACHANDRAN	NO	NO	YES	NO	NO	NO
35	HAMSA KUNJU	NO	NO	NO	NO	NO	NO
36	THANGAVAL	NO	N0	NO	NO	NO	NO
37	VELAYUDHAN	YES	NO	NO	NO	YES	yes
38	SEBASTIAN	YES	MI	YES	NO	NO	NO
39	SKARIA	YES	NO	YES	NO	NO	yes
40	LICY VINIOLA	NO	N0	N	NO	NO	NO
41	STEPHENSOS	YES	ARRYTHMIA	NO	NO	NO	NO
42	GANGADHARAN	NO	N0	NO	NO	NO	NO
43	SUNDERESAN	NO	N0	YES	NO	NO	NO
44	THANKAYYAN	NO	N0	NO	SSI	NO	NO
45	MAHILAMANI	NO	N0	N	NO	NO	NO
46	ROY CHERIAN	NO	N0	NO	NO	NO	NO
47	KURUVILLA	NO	N0	NO	NO	NO	NO
48	SAJI KUMAR	NO	N0	NO	NO	YES	NO
49	RAJAGOPALAN	YES	N0	YES	NO	NO	NO
50	KAMARUDEEN	YES	ARRYTHMIA	yes	NO	NO	NO
51	RAJAN NK	YES	MI	NO	NO	NO	NO
52	KALIDHAS	NO	NO	NO	NO	NO	YES

s. no	NAME	DURATION OF STAY	OUTCOME	FOLLOW UP	ISSUES	ejection fraction
1	PANKAJAKSHAN	9	DISCHARGE	21	ILEUS	74%
2	KOCHAPPAN	8	DISCHARGE	33		67%
3	NARAYAN P	10	DISCHARGE	30	BLEEDING	60%
4	BABU M	2	DEATH	NA	BLEEDING	60%
5	DIVAKARN N	16	DISCHARGE	10	ALI	70%
6	ANANTHU MA	9	DISCHARGE	4		67%
7	KRISHNA K P	6	DISCHARGE	26	NO	74%
8	SUKUMARA PILLAI	8	DISCHARGE	18		60%
9	SULAIMAN AM	8	DISCHARGE	17	NO	64%
10	MOHANAN NAIR	8	DISCHARGE	18		60%
11	MATHEW VARGHESE	10	DISCHARGE	24	ILEUS/LRTI	77%
12	POCKER	9	DISCHARGE	3		50%
13	S. BAGHEL	9	DISCHARGE	27	UTI	65%
14	KUNJUMON	8	DISCHARGE	26		68%
15	THAMPI	10	DISCHARGE	6	ATHEROEM	70%
16	GOMATHY	7	DISCHARGE	27		79%
17	PAPPACHAN	11	DISCHARGE	30	ILEUS	50%
18	KUMARAN KT	12	DISCHARGE	24	ILEUS	56%
19	**KARUNAK PILLAI**	14	DISCHARGE	27	ILEUS	70%
20	RASHEED	8	DISCHARGE	27		80%
21	MUSTAFA KUNJU	11	DISCHARGE	26	ILEUS	60%
22	MOHANAN M	8	DISCHARGE	27		60%
23	CHANCHAL RAJ	8	DISCHARGE	24		60%
24	gopi k	8	DISCHARGE	8		78%
25	SREEDHARAN NADAR	7	DISCHARGE	25		78%
26	ABUBAKER KP	8	DISCHARGE	18		56%
27	SHEEJA A	7	DISCHARGE	24		68%
28	SIVARAJAN	8	DISCHARGE	24		78%
29	MURALEEDHARAN N	8	DISCHARGE	24		67%
30	KARUNAKARAN K	7	DISCHARGE	3		50%
31	SHAMSHUDDEEN M	7	DISCHARGE	21		76%
32	MATHAI	10	DISCHARGE	22		78%

s. no	NAME	DURATION OF STAY	OUTCOME	FOLLOW UP	ISSUES	ejection fraction
33	J NADAR	2	DEATH	NA		68%
34	BALACHANDRAN	15	DISCHARGE	22	TRACHEOS	74%
35	HAMSA KUNJU	7	DISCHARGE	12		60%
36	THANGAVAL	6	DISCHARGE	19		63%
37	VELAYUDHAN	14	DISCHARGE	15	ALI	62%
38	SEBASTIAN	11	DEATH	NA	AKI	56%
39	SKARIA	14	DISCHARGE	15	ALI	58%
40	LICY VINIOLA	7	DISCHARGE	18		78%
41	STEPHENSOS	9	DISCHARGE	5		53%
42	GANGADHARAN	7	DISCHARGE	16		67%
43	SUNDERESAN	10	DISCHARGE	9		75%
44	THANKAYYAN	10	DISCHARGE	6		70%
45	MAHILAMANI	7	DISCHARGE	8		75%
46	ROY CHERIAN	14	DISCHARGE	13	ACUTE PAN	58%
47	KURUVILLA	11	DISCHARGE	3		61%
48	SAJI KUMAR	8	DISCHARGE	3		65%
49	RAJAGOPALAN	7	DISCHARGE	3		74%
50	KAMARUDEEN	16	DISCHARGE	2		56%
51	RAJAN NK	9	DISCHARGE	1		64%
52	KALIDHAS	11	DISCHARGE	1	GLUTEAL IS	70%