

**OUTCOME OF MEDICALLY MANAGED UNCOMPLICATED ACUTE
TYPE B AORTIC DISSECTION- A SINGLE CENTER
RETROSPECTIVE ANALYSIS**

Dr. SRIRAM MANCHIKANTI

MCh VASCULAR SURGERY THESIS

2020- 2022



SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM

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**OUTCOME OF MEDICALLY MANAGED UNCOMPLICATED ACUTE
TYPE B AORTIC DISSECTION- A SINGLE CENTER
RETROSPECTIVE ANALYSIS**

A THESIS SUBMITTED BY

Dr. SRIRAM MANCHIKANTI

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

MCh VASCULAR SURGERY

2020 - 2022

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Sriram Manchikanti hereby certify that I had personally carried out the work depicted in the thesis titled,

“Outcome of medically managed uncomplicated acute type B aortic dissection- a single center retrospective analysis”,

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.


Signature

Dr. Sriram Manchikanti

Date 12.8.2022.

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The thesis entitled, "Outcome of Medically managed uncomplicated Acute type B aortic dissection- A single center retrospective analysis" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

*Clearance was obtained from the Institutional Ethics Committee / Institutional Animal Ethics / Institutional Committee for Stem Cell Research / Other appropriate committees (if any, specify) for carrying out the study.

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Date 12/8/2022

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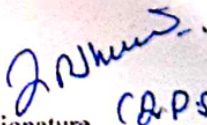
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*Clearance was obtained from the Institutional Ethics Committee


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APPROVAL OF THE THESIS

The thesis entitled

“Outcome of Medically managed uncomplicated Acute type B aortic dissection-
A single center retrospective analysis”

Submitted by

Dr Sriam Manchikanti

for the degree of **MCh Vascular Surgery**

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(Name & Signature of the Guide)

(Name & Signature of thesis examiner)

ACKNOWLEDGEMENTS

With the blessing of Lord Venkateshwara.

I would like to thank my Guides and teachers Dr. P Shivanesan and Dr. Varghese T Panicker for helping me and guiding me through the entire 3 years and their patience and constant support for helping me with the thesis.

I would like to thank my colleagues and seniors in the Department Dr. Vinith, Dr. Ashutosh, Dr. Neelam, Dr. Aditya, Dr. Akash and Dr Sandeep for their help and support.

I would like to thank my friend Dr. Akash Joshi my batchmate, who walked the same path during the thesis submission.

Nothing is possible without the support of my parents and my sister.

I would like to express my gratitude to all those who helped me in this journey of the thesis.

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LIST OF ABBREVIATIONS

| Serial No. | Abbreviation | Full Form |
|-------------------|---------------------|--|
| 1. | ABAD | Acute type B aortic dissection |
| 2. | BP | Blood pressure |
| 3. | CAD | Coronary artery disease |
| 4. | CKD | Chronic kidney disease |
| 5. | COPD | Chronic obstructive pulmonary disorder |
| 6. | CVA | Cerebrovascular accident |
| 7. | DBP | Diastolic blood pressure |
| 8. | FDA | Food and Drug Administration |
| 9. | OMT | Optimal medical therapy |
| 10. | SBP | Systolic Blood Pressure |
| 11. | TEVAR | Thoracic endovascular aneurysm repair |

SYNOPSIS

OUTCOME OF MEDICALLY MANAGED UNCOMPLICATED ACUTE TYPE B AORTIC DISSECTION- A SINGLE CENTER RETROSPECTIVE ANALYSIS

SYNOPSIS

BY

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TECHNOLOGY, TRIVANDRUM

SYNOPSIS

Background: Type B dissections are those where the tear begins distal to the left subclavian artery¹. Acute uncomplicated Type B dissection is treated medically. There is considerable debate as to the optimal management of type B dissection in the chronic phase. If left untreated, some patients tend to have post dissection aneurysms with the complications of rupture and some heal completely with medical management.

Materials and Methods: The purpose of our study is to retrospectively look at long term outcomes of patients with type B aortic dissection managed conservatively (in the initial acute phase) and analyse the predictors for survival and those with mortality. The Study, Single centre retrospective observational study conducted in the division of vascular surgery in the Department of CVTS, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram from 2011 to 2021. A total of 33 patients on medically managed uncomplicated type B dissection were chosen as the study population; and their various demographic, clinical and imaging parameters were analysed and factors predicting survival and mortality were observed.

Results and observations: A majority belonged to the age group of 51 to 60 years (33.33%) and were males (78.79%) of the patients. The most common comorbidity hypertension was reported among 93.94%. 12.12% mortality among the study subjects, was observed. CKD was found to be a statistically significant predictor of mortality. Based on imaging features in the mortality group, 25% subjects had false lumen expansion, 50% had partial thrombosis. The absence of complete thrombosis of the false lumen implying that complete positive remodelling did not occur in these patients. In the surviving, 24.13% had near total to complete thrombosis, 48.27% had partial thrombosis, 17.24% had minimal thrombosis, and 6.89% had false lumen

expansion. In our study it was seen that mortality occurred when the size of the entry tear was greater than 16mm and another important aspect seen was in the patients surviving more than 5years the mean entry size diameter was less than 10mm.

Conclusion: Good percentage of patients surviving beyond 5 years of presentation with conservative management alone with predictors of mortality being CKD and large entry tears.

1. INTRODUCTION

Type B dissections are those where the tear begins distal to the left subclavian artery¹. The incidence of aortic dissection is 5 to 30 cases per 1 million people per year making it a relatively rare entity². These dissections despite having a low incidence, have significant variation in presentation from a patient who never makes it to the hospital with a rupture and complications including acute limb ischemia, acute kidney injury to acute mesenteric ischemia and in the similar continuum of presentation in the uncomplicated presentation with only pain and hypertension. Unlike Type A dissection where surgery remains a standard of care and in those complicated type B and acute type B dissections where standardized line of management is well established, there is considerable debate as to the optimal management of type B dissection in the chronic phase. If left untreated, some patients tend to have post dissection aneurysms with the complications of rupture and there are those fortunate who completely heal. In this variation of outcomes the recent role of Thoracic Endovascular Aneurysm Repair (TEVAR) has come under scrutiny. Like one size does not fit all, there is considerable debate as to what is the optimal management in these patients. The purpose of our study is to retrospectively look at long term outcomes of patients with type B aortic dissection managed conservatively (in the initial acute phase) and analyse the predictors for survival and those with mortality.

1.1 AIM OF THE STUDY

The aim of the study is to analyse the parameters of patients with uncomplicated type B dissections managed conservatively and

1. To determine the rate of intervention, morbidity and mortality associated with medically managed patients.
2. To find out factors that are predictive for need of intervention or of adverse outcome.

2. REVIEW OF LITERATURE

Type B dissections are those where the tear begins distal to the left subclavian artery and they commonly occur in the descending thoracic aorta.¹ The incidence of aortic dissection is 5 to 30 cases per 1 million people per year² making it relatively rare.

The mean age of presentation of Type B aortic dissection occurs between 50-65 years. Patients in the 3rd and 4th decade of life have commonly associated connective tissue disorders including Marfan`s and Ehler-Danlos syndrome.³ The most common risk factors associated with the development of aortic dissection is uncontrolled hypertension. The most common presentation of Type B dissection is chest pain and back pain. After the diagnosis of dissection is made the management of Type B dissection varies from the predominant surgical management of type A dissection . The type B dissections are classified as either uncomplicated or complicated to further help in the management of these patients. Complicated Type B dissections refer to aortic rupture, visceral or renal ischemia, lower extremities ischemia, or spinal cord ischemia (SCI). The expansion to the aortic arch or proximal descending aorta with total diameter of 4.5 cm or greater is also considered a complicated dissection.⁴ Absence of these features is called uncomplicated dissection. The duration of symptoms is also important with acute dissections defined as those less than 14 days of durations and occurring beyond 3 months are called chronic Type B dissections.

Management of acute uncomplicated type B dissections is initially medical consisting of sufficient pain control and reduction of the systolic blood pressure to less than 120 mm Hg or to the lowest level necessary to maintain vital functions.⁵ The management in chronic dissections is based on maximum thoracic aortic diameter. Those with diameters greater than 5.5 cm or a documented increase in the aortic diameter of more than 1 cm within 1 year is an indication for invasive treatment. If mal-perfusion, aortic rupture or progressive dissection occurs, a chronic aortic dissection should also be treated The management of chronic Type B

dissection is understood based on the natural history of the medically managed uncomplicated type B dissection.⁵ The initial studies done by DeBakey et al⁷ who showed that following the medical management of type B dissection over a period of time, majority of patients eventually have aneurysmal degeneration needing intervention. In the study done by Juvonen et al⁸ who followed up 50 chronic type B dissection for a median follow up of 40 months they observed that 20% of patients developing aneurysmal degeneration and 9 out of the 50 developed fatal rupture of the aneurysms another important finding in this group was median descending aortic diameter before rupture in the rupture group was 5.4 cm (range 3.2-6.7 cm). Guido et al⁹ observed that even in uncomplicated Type B dissection delayed aortic dilation occurs in 20-50% with adequate antihypertensive therapy. These studies have brought into consideration of whether the need for prophylactic TEVAR is needed in these patients and further questions arose on the timing of TEVAR in those patients with uncomplicated Type B dissection. Juvonen et al⁸ observed the diameter of 5.4cm corresponds to high likelihood of complications including rupture.

Similarly, the predictors of those developing aortic dilatation at a more rapid rate were age less than 60 years, Marfans syndrome and FDP \geq greater than 20ug/ml at admission. Slower rate of growth was seen in patients with age greater than 60years, tight heart rate control and use of calcium channel blockers. Morphological predictors of aortic dilatation were aortic diameter \geq 40mm, proximal descending thoracic false lumen greater than 22mm, saccular formation of false lumen, one entry tear, large \geq 10mm tear at the initiation of dissection, false lumen located along the inner aortic curvature and areas with ulcer like projections. Based on the inferences of the above study the importance of imaging and best medical management is of paramount importance. The first choice of management in these patients is best medical management along with close follow up for evidence of complications. In a study done by Lou et al¹⁰ they observed that even with best medical management the mortality rates were not

acceptable. To address whether additional TEVAR was beneficial various trials were done.¹² The INSTEAD trial which had one hundred forty patients in stable clinical condition at least 2 weeks after index dissection randomly subjected to elective stent-graft placement in addition to optimal medical therapy (n=72) or to optimal medical therapy alone (n=68) with surveillance (arterial pressure according to World Health Organization guidelines $\leq 120/80$ mm Hg)¹³. The primary end point was all-cause death at 2 years. The trial found no significant difference between TEVAR and optimal medical therapy for death, reintervention or adverse events. The criticism of the study was that it included patients with acute or chronic uncomplicated type B aortic dissection.

ADSORB trial was the first randomized controlled trial on acute aortic dissection and compares OMT with OMT plus TEVAR, performed with the aim to cover the primary entry tear in patients with uncomplicated ABAD. At 1 year this too did not show any difference in survival.¹⁴

Based on this data Dong et al¹⁵ studied the long term results of TEVAR for type B dissection. In their mean follow up of 68.1 \pm 22.9 months after TEVAR they observed that interventions in the subacute group was statistically lower than in the acute and the chronic group. In the study done by Tefera et al¹⁶, they observed that early mortality rate with best medical management was 1.6% compared to the 37% in the group with complications.

Based on these studies it is clear that there is definite evidence when to intervene for chronic type b dissection on follow up. But there is limited evidence for the role of TEVAR¹⁷, the optimum timing of TEVAR in uncomplicated type B dissections and the extent of stent coverage. The objective of our study is to find these factors that predict the need for future intervention.

3. MATERIALS AND METHODS

The present study was approved by the institute research and ethics committee. It was conducted in the division of vascular surgery in the Department of CVTS, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram. The study was conducted in a period of last 10 years starting from January 2011 up to December 2021. The data was collected from hospital database.

Study design: Single centre retrospective observational study.

Population: A total of 33 patients on medically managed uncomplicated type B dissection were chosen as the study population and their various demographic, clinical and imaging parameters were analysed.

Inclusion criteria:

- Patients with uncomplicated type B aortic dissection who were managed medically

Exclusion criteria:

- Patients who had any complications at presentation such as aortic rupture, malperfusion, uncontrolled pain or uncontrolled hypertension.
- Patients who had previous Type A dissection or other aortic surgery.
- Patients with connective tissue disorders for example Marfans syndrome.

3.1 Institute Protocol for management of Type B dissection:

All patients diagnosed with Acute type B dissection are initially evaluated for cardiac status, clinical, biochemical and imaging parameters to look for any complications or mal-perfusion. If any mal-perfusion or complications present they are immediately managed with the appropriate intervention. If the patient is diagnosed to have an uncomplicated aortic dissection then the patient is admitted and managed medically.

The medical management is called as an anti-impulse therapy and attributed to the work of Veith and Palmer. The regimen aims to reduce the cardiac contractility and control the hypertension to reduce the pressure that drives the expansion of the false lumen. The anti-impulse therapy consists of Antihypertensives with parenteral antihypertensives mainly betablockers with strict blood pressure monitoring with the aim of reducing the blood pressure to a systolic blood pressure less than 120mm Hg and Heart rate of 60 to 70. Analgesics are also an important part in the treatment and sometimes intravenous morphine infusions are used. Once adequate pain management and blood pressure control is achieved the patient is slowly tapered to oral antihypertensives and discharged with a strict advise of blood pressure control and is reviewed after 1 month with imaging. If there is no progression from the initial imaging then a subsequent one repeated at 6 months and then yearly . Repeat imaging is stopped if there is complete obliteration of false lumen.

In the course of follow up those patients that developed complications or post dissection aneurysms were taken for intervention.

3.2 APPROVAL FROM TECHNICAL ADVISORY COMMITTEE

TAC approval was taken prior to starting the study.

3.3 APPROVAL FROM INSTITUTIONAL ETHICS COMMITTEE

IEC approval was taken prior to starting the study.

4. METHODOLOGY

Patients who satisfied the inclusion criteria were included. Data collected from the hospital data system and hospital records were analysed. The patient data was collected and entered into a patient Performa chart.

Following data of variables were collected for the study:

4.1 Patient Performa sheet

1. Date & Serial Number:
2. Age/ sex:
3. Address:
4. Phone no.:
5. Presentation:

| First symptom | Date of symptom onset | Associated symptoms | Date of presentation to nearest hospital | Any management | Date of presentation in SCTIMS |
|---------------|-----------------------|--|--|----------------|--------------------------------|
| | | <ul style="list-style-type: none"> • Syncope:(y/n) • Palpitations:(y/n) • Chest pain:(y/n) • Giddiness: (y/n) • Abdominal pain:(y/n) • Pain in extremity:(y/n) | | | |

6. Comorbid conditions:

| Condition | Present/absent | Duration | Current management |
|-------------------|----------------|----------|--------------------|
| Diabetes mellitus | | | |
| Hypertension | | | |
| COPD | | | |
| CAD | | | |
| CKD | | | |

| | | | |
|-----------------------------|--|--|--|
| CVA | | | |
| Tobacco usage | | | |
| Peripheral vascular disease | | | |

7. Family history: (of aortic dissection/ sudden death and comorbid conditions)

8. Examination at presentation:

| | |
|-------------|--|
| Pulse | |
| BP | |
| CVS | |
| Respiratory | |
| Abdomen | |

| Peripheral pulses | Right | Left |
|-------------------|---------|------|
| | Carotid | |
| Brachial | | |
| Radial | | |
| Ulnar | | |
| Femoral | | |
| Popliteal | | |
| ATA | | |
| PTA | | |
| DPA | | |

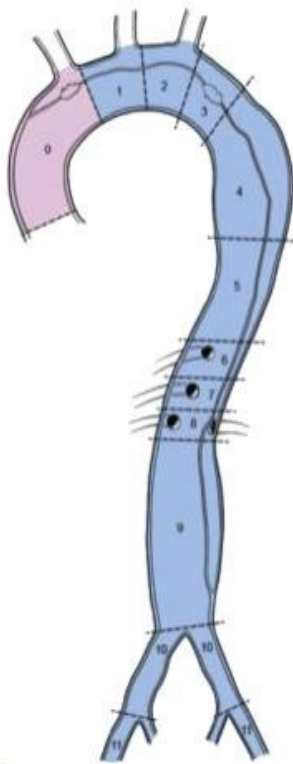
9. 2D echo(date):

10. If admission done (yes/no):

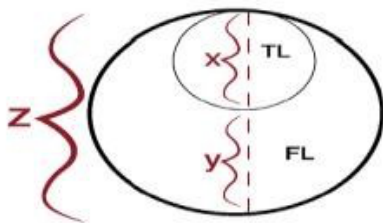
11. Antihypertensives started at the time:

12. CT scan: diameters at the various marked points: (date of scan):

| | |
|-------------------------------|--|
| Arch type | |
| Type of innominate artery | |
| Subclavian artery orientation | |
| Size of entry tear | |
| Zone of entry tear | |
| Other entry tears | |
| False lumen diameter | |
| True lumen | |

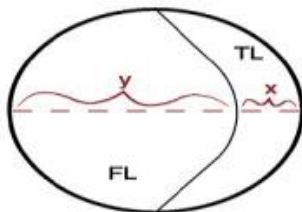


| Type | Proximal Extent | Distal Extent |
|--|-----------------|---------------|
| A_D Entry tear: Zone 0 | 0 | 0 |
| | 1 | 1 |
| | 2 | 2 |
| | 3 | 3 |
| | 4 | 4 |
| B_{PD} Entry tear: ≥ Zone 1 | 5 | 5 |
| | 6 | 6 |
| | 7 | 7 |
| | 8 | 8 |
| | 9 | 9 |
| I_D Unidentified entry tear involving Zone 0 | 10 | 10 |
| | 11 | 11 |
| | 12 | 12 |

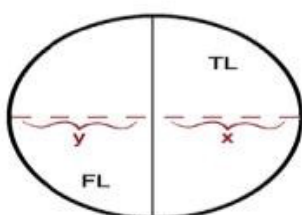


Acute Circumferential Delamination

x = True Lumen Diameter
 y = False Lumen Diameter
 z = Total Aortic Diameter
 $x + y = z$

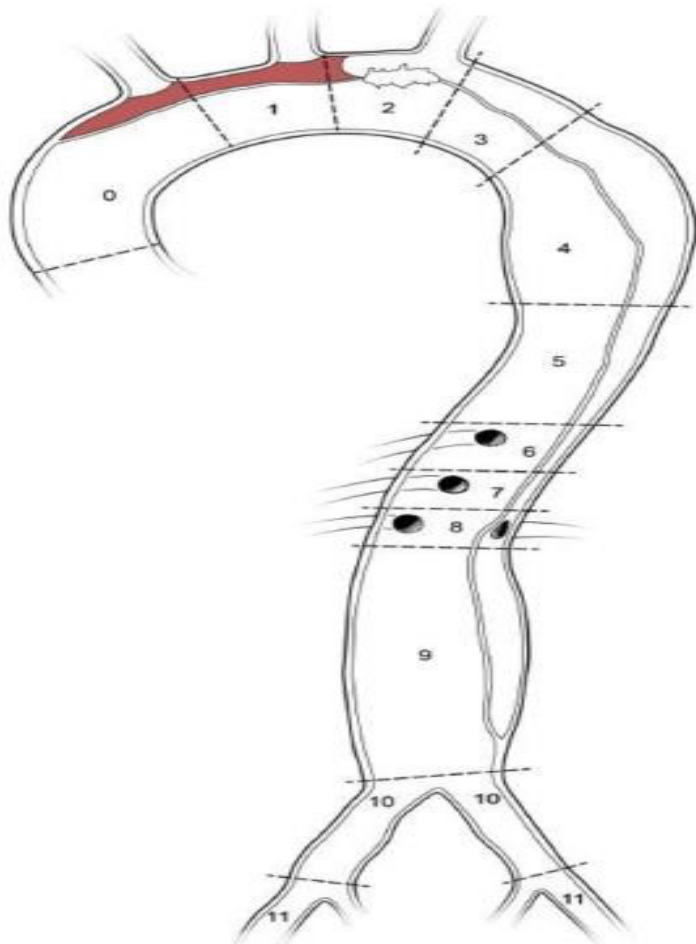


Acute Concave



Chronic Straight Septum

1
2
3
4
5
6
7
8
9
10
11



13. Follow up imaging:

| | | | | |
|----------------------|--|--|--|--|
| Date | | | | |
| Lumen type | | | | |
| Extent of thrombosis | | | | |

| | | | | |
|--|--|--|--|--|
| Diameter at point 1. (true/false/total) | | | | |
| 2. (true/false/total) | | | | |
| 3. (true/false/total) | | | | |
| 4. (true/false/total) | | | | |
| 5. (true/false/total) | | | | |

| | | | | |
|-----------------------|--|--|--|--|
| 6. (true/false/total) | | | | |
| 7. (true/false/total) | | | | |
| 8. (true/false/total) | | | | |
| 9. (true/false/total) | | | | |

| | | | | |
|---------------------------|--|--|--|--|
| 10. (true/false/total) | | | | |
| 11. (true/false/total) | | | | |
| 12. (true/false/total) | | | | |
| 13. (true/false/total) | | | | |
| 14. Any vessel thrombosis | | | | |

14. Follow up with symptoms/routine:

- Nature of symptoms:
- Intervention done:
- BP:
- HR:
- Pulse deficit:
- Adjunctive imaging:
- Outcome:
- Any medication added:

15. Any intervention done:

- Type of intervention:
- Indication for intervention:
- Any findings during the intervention:
- Outcome of intervention:

16. Final outcome at the time of follow-up:

17. Any death in the course of follow-up: including cause:

5. STATISTICAL ANALYSIS

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Non normally distributed quantitative variables were summarized by median and interquartile range. Data was represented using appropriate diagrams like bar diagrams, pie diagrams and box plots.

All quantitative variables were checked for normal distribution within each category of explanatory variables using histograms and plots.

Categorical outcomes were compared between study groups using chi square test and Fischer exact test. P value <0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Kaplan Meier survival analysis was done to perform overall survival rate.

6. OBSERVATION AND RESULTS

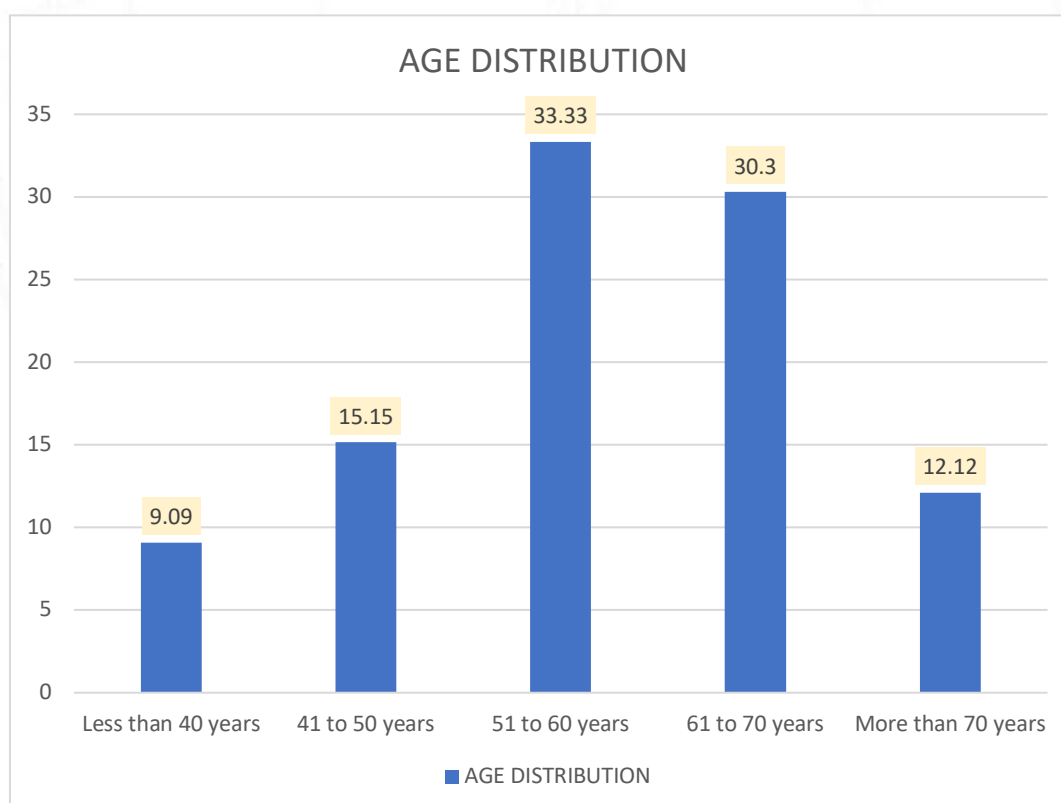
6.1 Age Distribution:

We observed that majority of the study subjects belonged to the age group of 51 to 60 years (33.33%), followed by 61 to 70 years (30%), and 41 to 50 years (15.15%). The mean age of the study subjects was 57.51years.

Table 1: Age distribution

| Age distribution | Number of subjects | Percentage |
|--------------------|--------------------|---------------|
| Less than 40 years | 3 | 9.09 |
| 41 to 50 years | 5 | 15.15 |
| 51 to 60 years | 11 | 33.33 |
| 61 to 70 years | 10 | 30.30 |
| More than 70 years | 4 | 12.12 |
| Total | 33 | 100.00 |

Figure 1: Age distribution



6.2 Gender wise distribution:

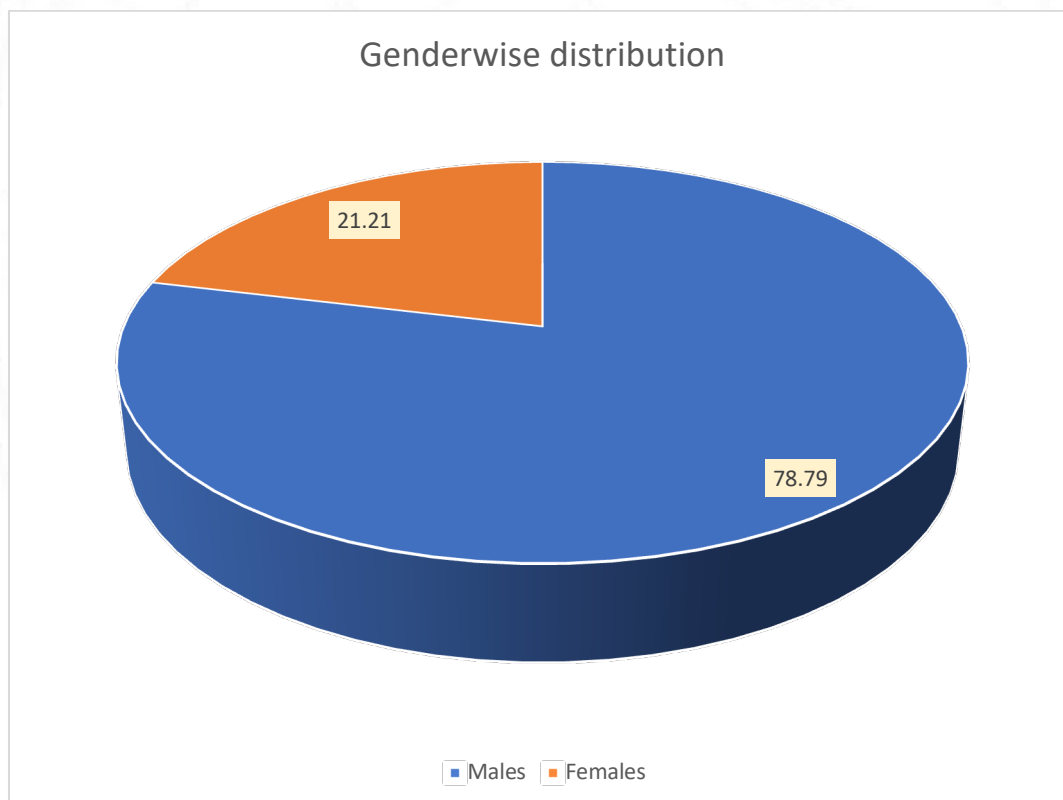
We observed that majority of the subjects were males (78.79%). 21.21% were females.

The male: female ratio in the current study was 3.71:1.

Table 2: Gender wise distribution

| Gender wise distribution | Number of subjects | Percentage |
|--------------------------|--------------------|------------|
| Males | 26 | 78.79 |
| Females | 7 | 21.21 |
| Total | 33 | 100.00 |

Figure 2: Gender-wise distribution



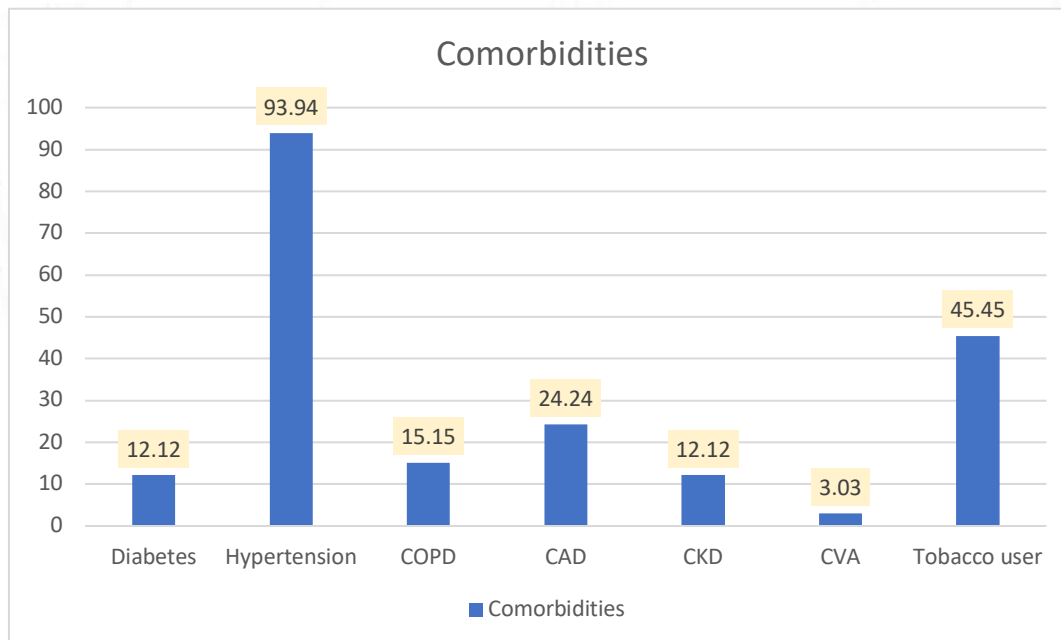
6.3 Comorbidities:

We observed that Diabetes was reported among 12.12% study subjects, Hypertension was reported among 93.94% study subjects, COPD was reported among 15.15% study subjects, CAD was reported among 24.24% study subjects, CKD was reported among 12.12% study subjects, CVA was reported among 3.03% study subjects.

Table 3: Comorbidities

| Comorbidities | Number of subjects | Percentage |
|---------------|--------------------|------------|
| Diabetes | 4 | 12.12 |
| Hypertension | 31 | 93.94 |
| COPD | 5 | 15.15 |
| CAD | 8 | 24.24 |
| CKD | 4 | 12.12 |
| CVA | 1 | 3.03 |
| Tobacco user | 15 | 45.45 |

Figure 3: Comorbidities



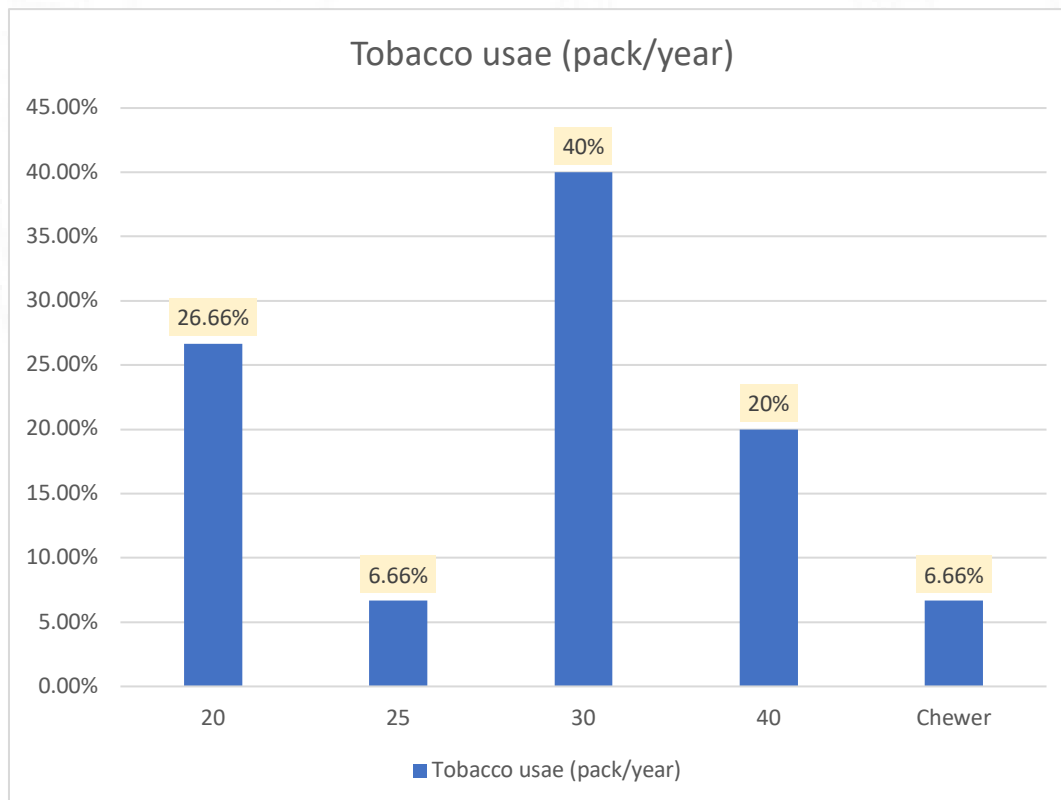
6.4 Tobacco usage in packs/year:

Tobacco usage in packs/year among the study subjects. We observed that 45.45% study subjects were tobacco users, out of which majority consumed an average of 30 packets per year (40%), followed by 23 packets per year (26.66%), and 40 packets per year (20%).

Table 4: Tobacco usage in packs/year

| Tobacco usage in packs/year | Number of subjects (n=15, tobacco users) | Percentage |
|------------------------------------|---|-------------------|
| 20 | 4 | 26.66% |
| 25 | 1 | 6.66% |
| 30 | 6 | 40% |
| 40 | 3 | 20% |
| Chewer | 1 | 6.66% |

Figure 4: Tobacco usage in packs/year



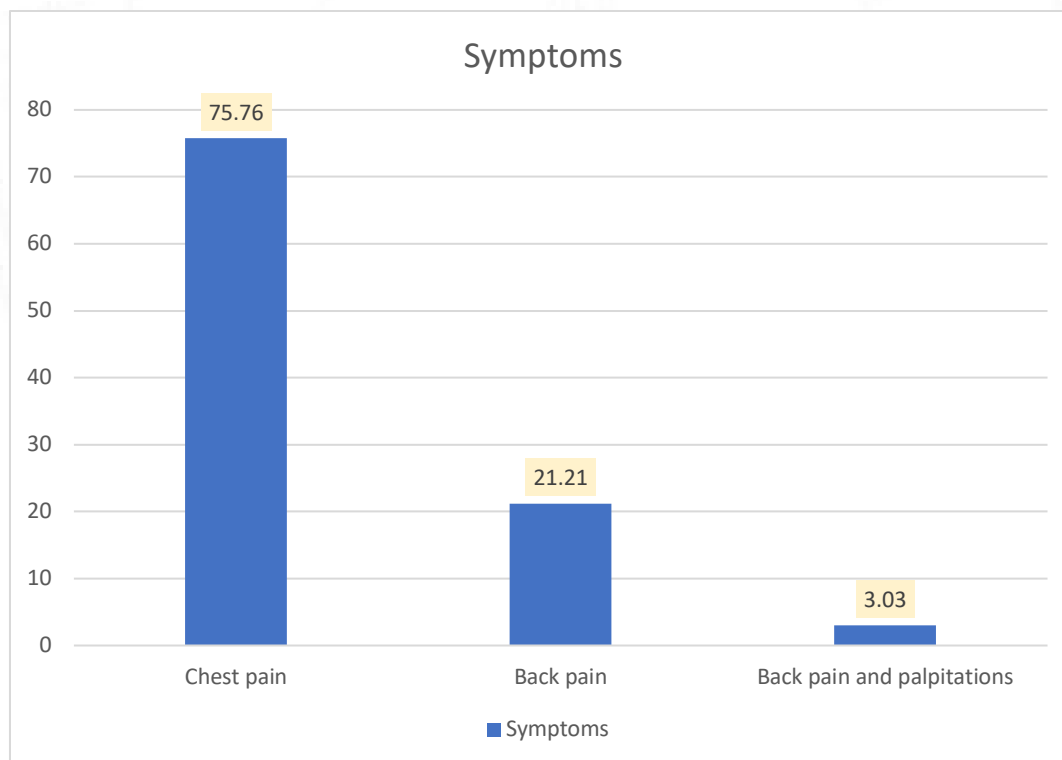
6.5 Clinical Presentation:

We observed that chest pain was the first and prominent symptom among 75.76% study subjects, followed by back pain among 21.21% and Back pain with palpitations among 3.03% study subjects.

Table 5: First symptom

| First symptom | Number of subjects | Percentage |
|----------------------------|--------------------|------------|
| Chest pain | 25 | 75.76 |
| Back pain | 7 | 21.21 |
| Back pain and palpitations | 1 | 3.03 |

Figure 5: First symptom



6.6 General Findings:

Table 6: General findings at presentation

| Parameter | Mean | SD |
|---------------------------------|-------------|-----------|
| Pulse | 90.54 | 14.84 |
| SBP | 147.57 | 23.59 |
| DBP | 87.87 | 15.96 |
| Size of entry tear in mm | 13.18 | 6.05 |

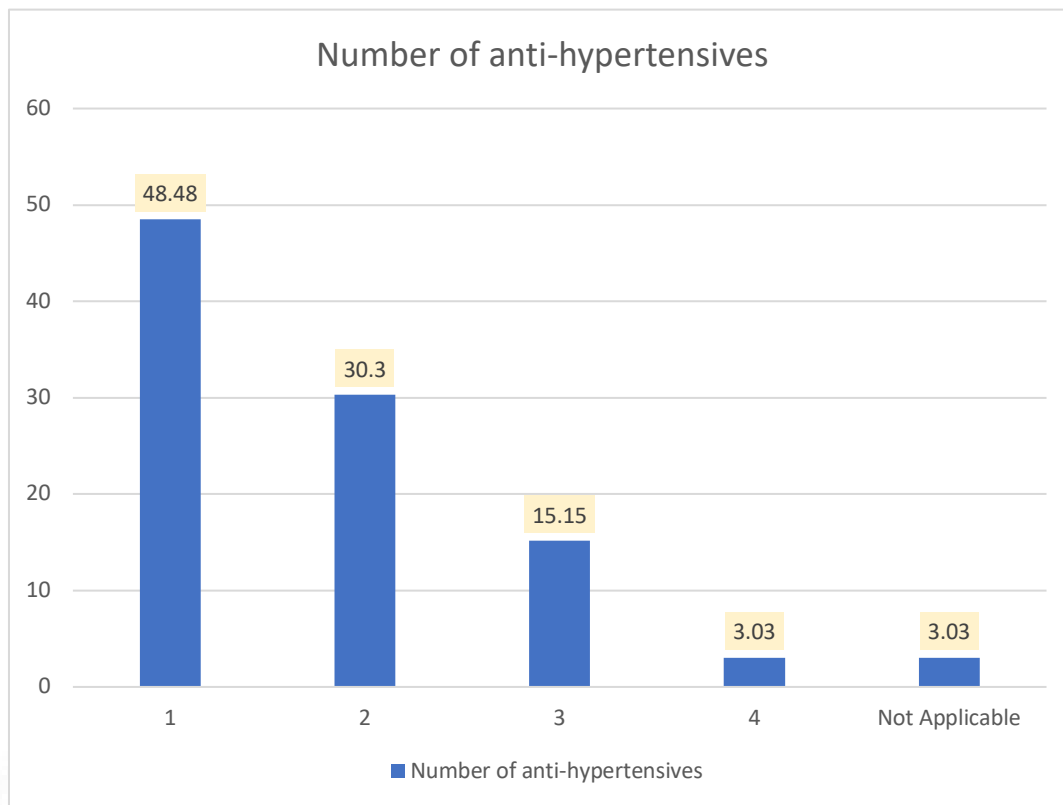
Number of Anti-hypertensives per patient

We assessed the Number of Anti-hypertensives per patient among the study subjects. We observed that majority of the study subjects were on single anti-hypertensive drug (48.48%), followed by two drugs among 30.30%, 3 drugs among 15.15% study subjects.

Table 7: Number of Anti-hypertensives per patient

| Anti-hypertensives no. | Number of subjects | Percentage |
|-------------------------------|---------------------------|-------------------|
| 1 | 16 | 48.48 |
| 2 | 10 | 30.30 |
| 3 | 5 | 15.15 |
| 4 | 1 | 3.03 |
| Not Applicable | 1 | 3.03 |

Figure 6: Number of Anti-hypertensives per patient



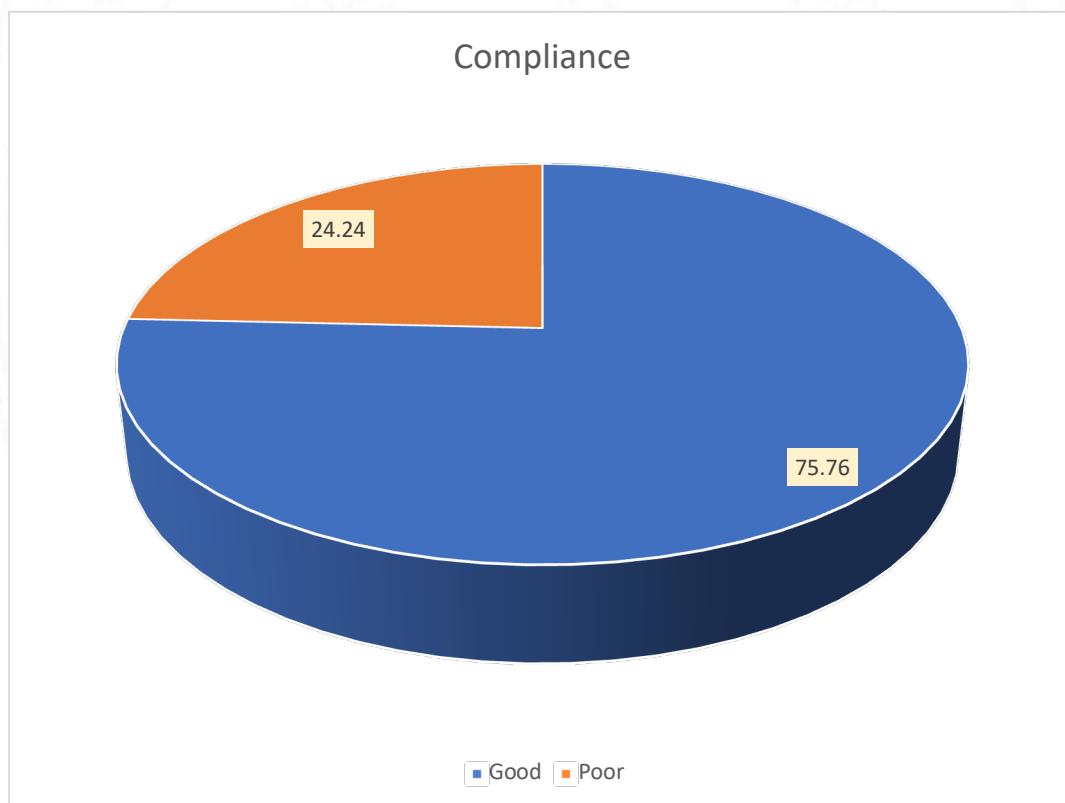
6.7 Patient Compliance:

In the current study we assessed the Compliance among the study subjects. We observed that 75.76% study subjects showed good compliance, while 24.24% showed poor compliance.

Table 8: Patient Compliance

| Patient Compliance | Number of subjects | Percentage |
|--------------------|--------------------|------------|
| Good | 25 | 75.76 |
| Poor | 8 | 24.24 |
| Total | 33 | 100.00 |

Figure 7: Patient Compliance



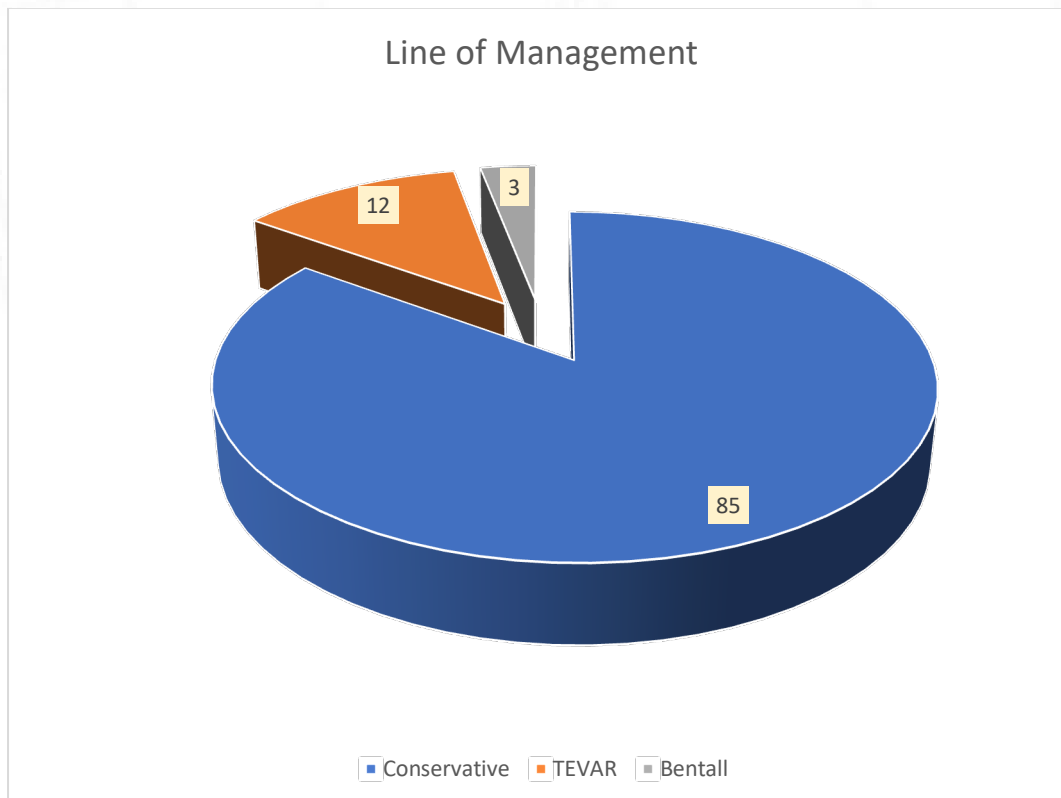
6.8 Line of Management

Conservative management was done among majority of the study subjects (85%), Intervention in the form TEVAR was performed among 12% and Bentall was considered among 3% study subjects. Bentall was done for severe AR ascending aortic aneurysm along with debranching and was planned as a bridge for eventual TEVAR. But the patient had a periprocedural mortality.

Table 9: Line of Management

| Line of Management | Number | Percentage |
|---------------------|--------|------------|
| Conservative | 28 | 85 |
| INTERVENTION(TEVAR) | 4 | 12 |
| Bentall | 1 | 3 |

Figure 8: Line of Management



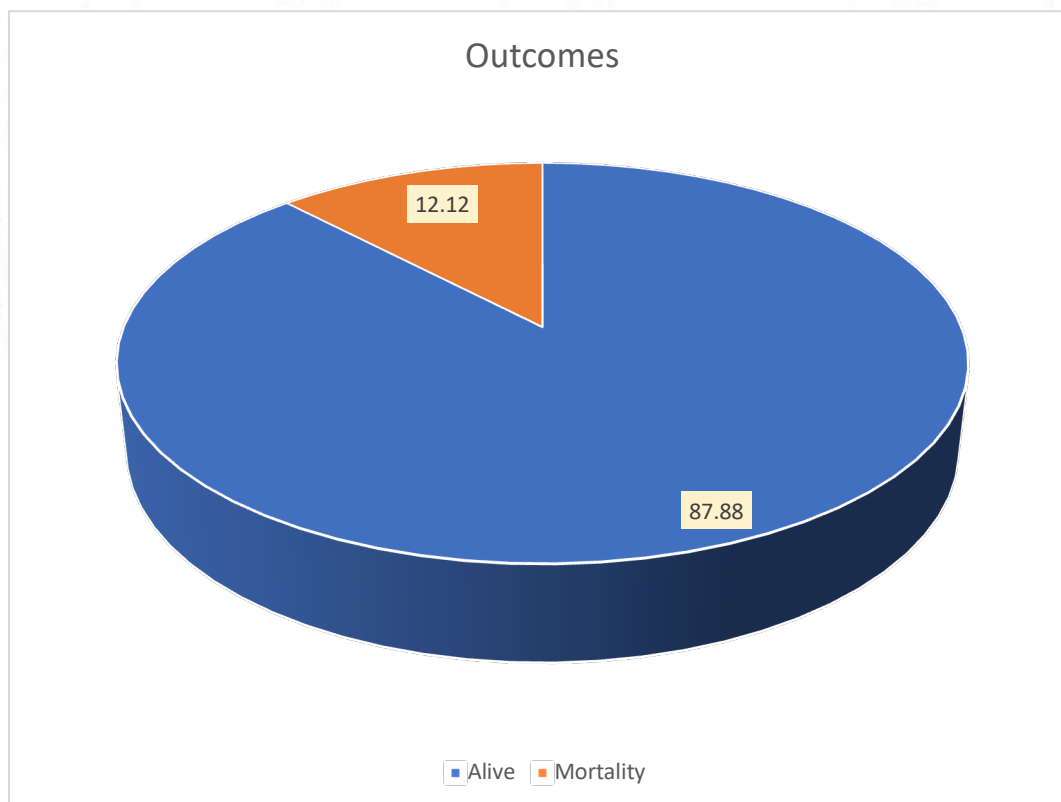
6.9 Outcome:

We observed 12.12% mortality among the study subjects, whereas 87.88% were alive. The 4 causes of mortality included 1 patient who died of periprocedural causes after surgery, another who developed pulmonary complications in the intervention group. In the conservative group it was observed that mortality in one patient was collapse during dialysis and another was due to COVID 19 complications.

Table 10: Outcome

| Outcome | Number of subjects | Percentage |
|-----------|--------------------|------------|
| Alive | 29 | 87.88 |
| Mortality | 4 | 12.12 |

Figure 9: Outcome

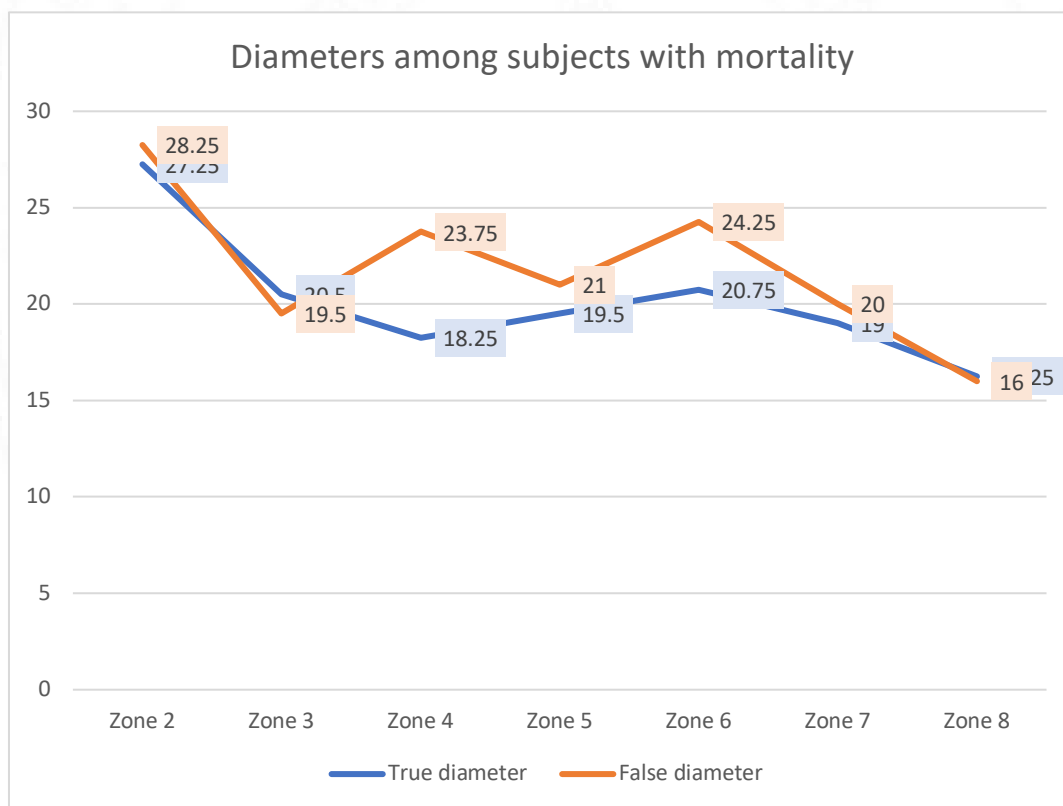


6.10 Comparison of aorta diameter with mortality:

Table 11: Comparison of largest diameter of aorta with mortality

| MORTALITY | | |
|-----------|-----------------------|----------------|
| Zones | Mean largest diameter | |
| | True diameter | False diameter |
| Zone 2 | 27.25 | 28.25 |
| Zone 3 | 20.50 | 19.50 |
| Zone 4 | 18.25 | 23.75 |
| Zone 5 | 19.50 | 21.00 |
| Zone 6 | 20.75 | 24.25 |
| Zone 7 | 19.00 | 20.00 |
| Zone 8 | 16.25 | 16.00 |
| Zone 9 | 16.00 | Not applicable |

Figure 10: Comparison of largest diameter of aorta with mortality



It was observed in the patients with mortality, there was a larger false lumen diameter compared to the true lumen.

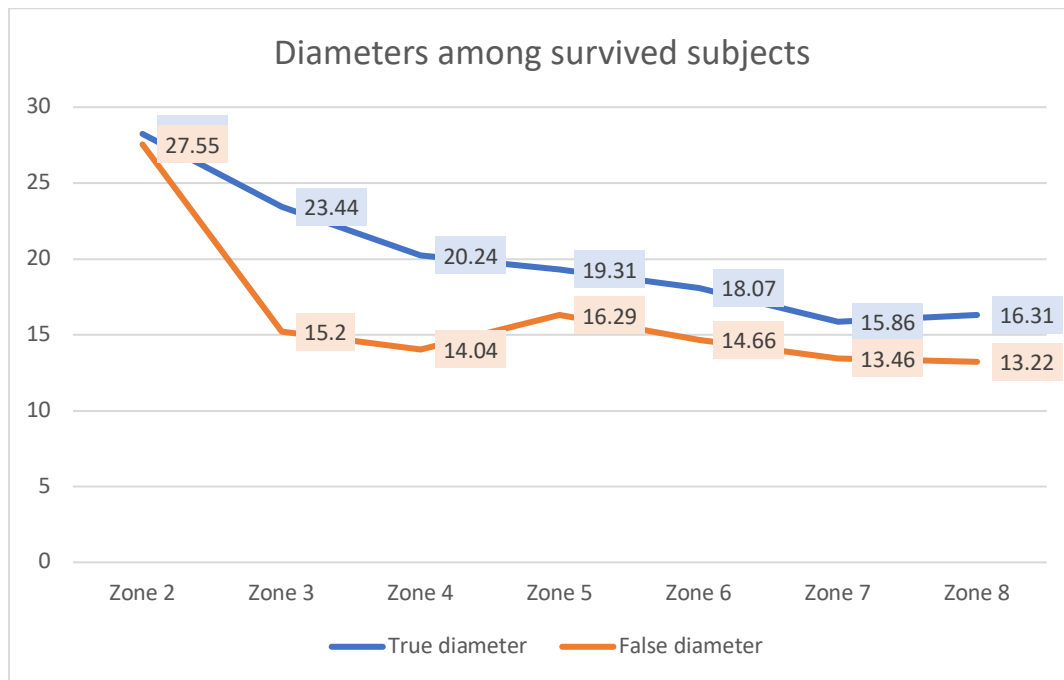
6.11 Comparison of aorta diameter with survival:

Table 12: Comparison of largest diameter of aorta with survival

The table shows in the groups with survival there is an overall larger true lumen diameter and smaller false lumen diameter

| ALIVE | | |
|--------------------------|------------------------------|-----------------------|
| Location (points) | Mean largest diameter | |
| | True diameter | False diameter |
| Zone 2 | 28.24 | 27.55 |
| Zone 3 | 23.44 | 15.20 |
| Zone 4 | 20.24 | 14.04 |
| Zone 5 | 19.31 | 16.29 |
| Zone 6 | 18.07 | 14.66 |
| Zone 7 | 15.86 | 13.46 |
| Zone 8 | 16.31 | 13.22 |
| Zone 9 | 14.56 | NA |

Figure 11: Comparison of largest diameter of aorta with survival



6.12 Comparison of various factors with mortality:

Various factors were evaluated as predictors for mortality in this study. The comorbidities, hypertension, COPD, CKD were studied and proportion of mortality was calculated. There was no significant difference observed in mortality among those who suffered from hypertension and COPD. Mortality was found to be higher in cases who suffered from CKD. In the study of echo findings it was noted that 100% mortality was observed in EF less than or equal to 60 but it was insignificant statistically as 62.07% cases alive also had EF less than or equal to 60. No significant difference observed in EF more than 60. As far as true lumen is concerned there was significant difference observed in reduction in size while no statistically significant difference observed in expansion and static true lumen at entry.

Table 13: Comparison of various factors with mortality

| <i>Comparison of various factors with mortality</i> | <i>Mortality</i> | | <i>Alive</i> | | <i>P - value</i> |
|---|---------------------------|---------------|---------------------------|----------------|------------------|
| | <i>Number of subjects</i> | <i>%(n=4)</i> | <i>Number of subjects</i> | <i>%(n=29)</i> | |
| <i>Hypertension</i> | 3 | 75.00 | 28 | 96.55 | 0.09 |
| <i>COPD</i> | 1 | 25.00 | 4 | 13.79 | 0.56 |
| <i>CKD</i> | 2 | 50.00 | 2 | 6.90 | 0.013 |
| <i>Expansion</i> | 1 | 25.00 | 6 | 20.69 | 0.84 |
| <i>Reduction in size</i> | 1 | 25.00 | 1 | 3.45 | 0.09 |
| <i>Static</i> | 1 | 25.00 | 8 | 27.59 | 0.91 |

6.13 Factors responsible for healing and mortality

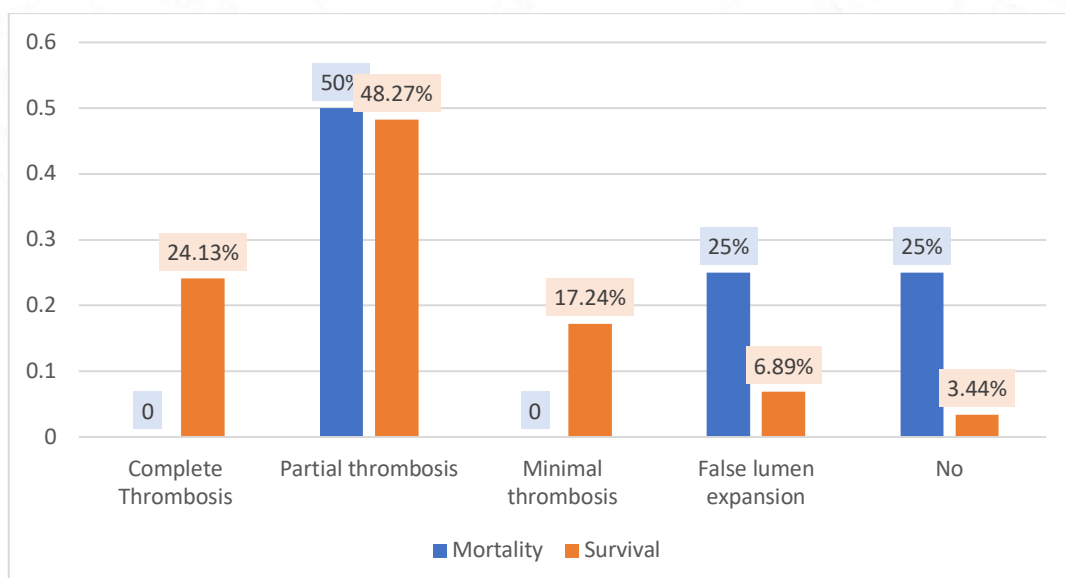
6.13.1 Presence of thrombosis

Among mortality, 25% subjects had false lumen expansion, 50% had partial thrombosis. While among alive subjects 24.13% had near total to complete thrombosis, 48.27% had partial thrombosis, 17.24% had minimal thrombosis, and 6.89% had false lumen expansion. So more rate of false lumen thrombosis and true lumen expansion seen in patients who were alive.

Table 14: Comparison of false lumen characteristics among survivors and mortality group

| Thrombosis | Mortality | Alive |
|-----------------------|-----------|-------------|
| Complete Thrombosis | 0 | 7 (24.13%) |
| Partial thrombosis | 2 (50%) | 14 (48.27%) |
| Minimal thrombosis | 0 | 5 (17.24%) |
| False lumen expansion | 1 (25%) | 2 (6.89%) |
| No | 1 (25%) | 1 (3.44%) |
| Total | 4 (100%) | 29 (100%) |

Figure 12: Comparison of false lumen characteristics among survivors and mortality group



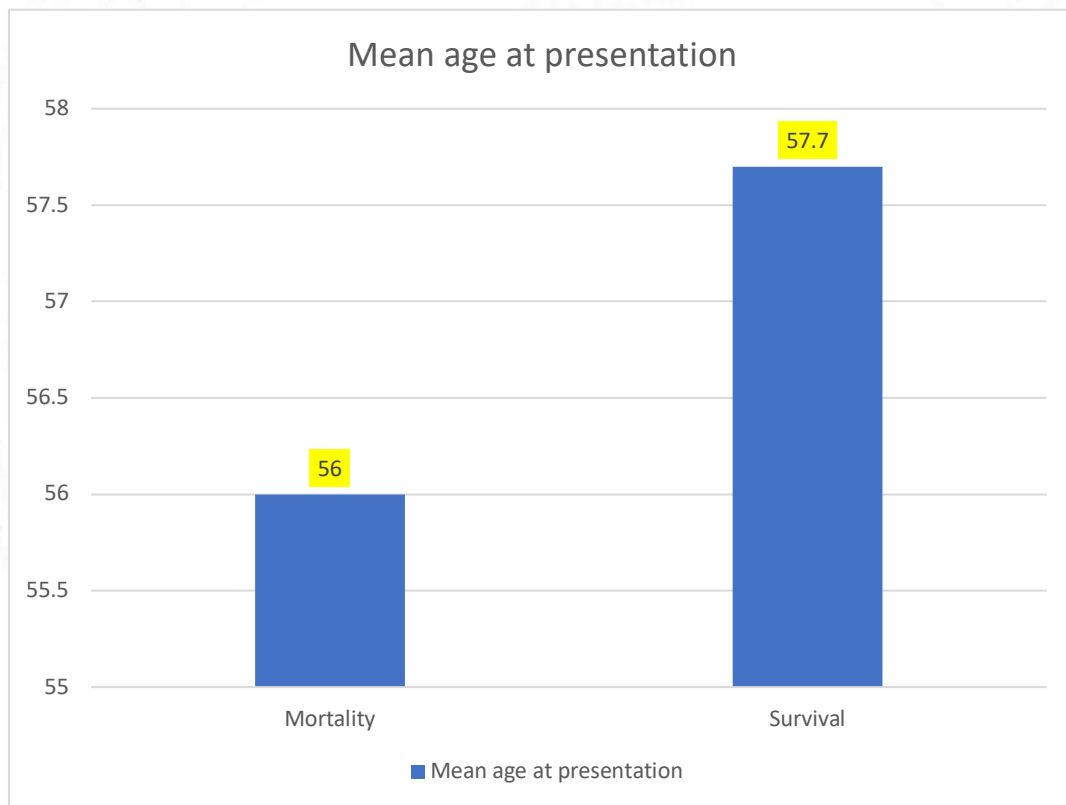
6.13.2 Mean age at presentation

Table 15: Mean age at presentation of the groups

The table compared the age of presentation with type B dissection with the group having mortality and the survivor group

| Age at presentation | Mean age at presentation | SD |
|---------------------|--------------------------------|------|
| Mortality | 56.0 | 15.5 |
| Survival | 57.7 | 10.1 |
| Significance | p-value: 0.3 (not significant) | |

Figure 13: Mean age of presentation in the two groups



6.14 Factors associated with survival

In the current study we assessed the various factors associated with survival. We observed that the mean age at the time of presentation among survivors was 57.72 years (median: 58 years), 93.1% were hypertensives, 20.68% had cardiac disorders, mean size of entry tear in mm was 12.39 mm, 79.31% subjects had good compliance, 3.44% subjects reported reduction in lumen size, and 20.68% had expansion of lumen.

Table 16: Parameters associated with survival

| Parameters among survived | | Observations |
|----------------------------------|---------------------------------|-----------------------------------|
| Gender | Males | 23 (88.46%) |
| | Females | 6 (85.71%) |
| Age at presentation | | 57.72 years (median: 58 years) |
| Comorbidities | Hypertension | 27 (93.10%) |
| | Cardiac disorders | 6 (20.68%) |
| Other factors | Size of entry tear in mm | 12.39 mm |
| | No. Of antihypertensives | 1.62 |
| | Good Compliance | 23 (79.31%) |
| True lumen | Expansion | 6 (20.68%) |
| | Reduction in size | 1 (3.44%) |
| | Static | 8 (27.58%) |

6.14.1 Comparison of survival duration with various parameters

We classified the survival into three groups: up to 3 years, 3 to 5 years, and more than 5 years. And compared the survival duration among the three groups. The age at presentation, gender, presence of comorbidities appeared to not to be associated with survival

Mean entry size was found to be inversely correlated with survival of the subjects (lesser the mean entry tear size, more was the survival duration). Also comparatively subjects with good compliance had more survival.

Table 17: Comparison of parameters in the 3 survival groups

| Parameters among survived | | Survival duration | | |
|---------------------------|--------------------------------|------------------------------|---------------------|-------------------------|
| | | Upton 3 year survival (n=12) | 3 to 5 years (N=12) | More than 5 years (n=9) |
| Gender | Males | 10 | 10 | 6 |
| | Females | 2 | 2 | 3 |
| Age at presentation | | 54.91 years | 60.91 years | 56.44 years |
| Comorbidities | Hypertension | 11 (91.67%) | 12 (100%) | 8 (88.89%) |
| | Cardiac disorders | 2 (16.67%) | 3 (25%) | 3 (33.33%) |
| Other factors | Size of entry tear in mm | 15.16 mm | 12.66 mm | 9.77 mm |
| | No. Of antihypertensive (mean) | 1.9 | 1.66 | 1.55 |
| | Good Compliance | 9 (75%) | 9 (75%) | 7 (77.78%) |
| True lumen | Expansion | 2 (16.67%) | 2 (8.33%) | 3 (33.33%) |
| | Reduction in size | 0 | 1 (%) | 1 (11.11%) |
| | Static | 5 (41.67%) | 4 (33.33%) | 0 |

6.15 Correlation between survival duration and various parameters

We also studied correlation between survival duration with various parameters (Pearson's between two quantitative parameters, and Spearman's correlation between Ordinal and quantitative parameters). We did not observe significant correlation between various parameters as mentioned in the following table.

Table 18: Correlation between survival duration and various parameters

| Correlation between survival duration and various parameters | Survival duration | |
|--|-------------------------|---------|
| | Correlation coefficient | P-value |
| Entry tear size | -.287 | .106 |
| Age at presentation | -.080 | .659 |
| Number of antihypertensives | -.135 | .455 |
| Outcomes | .059 | .746 |

6.16 Kaplan-Meier Survival Analysis

In the current study we again compared the survival duration with various parameters. We observed that mortality was greater when the entry tear size was greater than 16 mm (As mentioned in the following table). However due to lesser samples, we could not obtain further significance.

Similarly with various other parameters, we could not get statistical significance.

Table 19: Kaplan-Meier Survival Analysis

| Entry Tear Size (mm) | | Time | Status | Cumulative Proportion Surviving at the Time | |
|----------------------|---|--------|--------|---|------------|
| | | | | Estimate | Std. Error |
| 4.00 | 1 | 1.080 | Alive | .500 | .354 |
| | 2 | 2.000 | Alive | .000 | .000 |
| 5.00 | 1 | .170 | Alive | .000 | .000 |
| 6.00 | 1 | 1.000 | Alive | .667 | .272 |
| | 2 | 2.170 | Alive | .333 | .272 |
| | 3 | 10.000 | Alive | .000 | .000 |
| 8.00 | 1 | .920 | Alive | .800 | .179 |
| | 2 | 1.000 | Alive | .400 | .219 |
| | 3 | 2.170 | Alive | .200 | .179 |
| | 4 | 6.250 | Alive | .000 | .000 |
| 10.00 | 1 | .010 | Alive | .500 | .354 |
| | 2 | 1.000 | Alive | .000 | .000 |
| 11.00 | 1 | .420 | Alive | .000 | .000 |
| 13.00 | 1 | 1.500 | Alive | .500 | .354 |
| | 2 | 2.750 | Alive | .000 | .000 |
| 14.00 | 1 | .420 | Alive | .000 | .000 |
| 15.00 | 1 | .580 | Alive | .500 | .354 |
| | 2 | 1.250 | Alive | .000 | .000 |
| 16.00 | 1 | .330 | Alive | .750 | .217 |
| | 2 | 1.170 | Death | .500 | .250 |
| | 3 | 2.080 | Alive | .250 | .217 |
| | 4 | 2.250 | Death | .000 | .000 |
| 18.00 | 1 | .170 | Alive | .667 | .272 |
| | 2 | 1.170 | Alive | . | . |
| | 3 | 1.170 | Alive | .000 | .000 |
| 20.00 | 1 | .500 | Death | .000 | .000 |
| 21.00 | 1 | .500 | Alive | .000 | .000 |
| 22.00 | 1 | .250 | Alive | .500 | .354 |
| | 2 | 6.920 | Alive | .000 | .000 |
| 23.00 | 1 | .420 | Death | .000 | .000 |
| 24.00 | 1 | 1.580 | Alive | .000 | .000 |

7. DISCUSSION

Aortic dissection occurs in 4 or 5 persons per 100,000 annually, making it the most common aortic emergency. Furthermore, 20% to 30% of patients affected die before hospital admission. Although substantial improvements have been made since **Morris et al** reported the first successful repair in 1963¹, immediate surgical correction has been relatively static dogma for the treatment of acute type A aortic dissection. Consensus for the treatment of type B aortic dissection, however, has been more dynamic.

Early attempts at repair of acute type B dissection included decompression of the false lumen by creation of distal re-entry in the iliac artery, cellophane wrapping, and intimal tear excision and aortic replacement¹. However, mortality with these strategies was markedly high, prompting Palmer and Wheat to introduce medical management focused on lowering systolic blood pressure and pulse as the standard of care.

Medical management with anti-impulse therapy has remained the preferred treatment option for uncomplicated acute type B dissection, with in-hospital mortality rates typically <10% with this strategy⁴. Although interventional therapies may struggle to improve on medical management in the acute setting, when one examines longer term follow-up data, the results of medical management are less satisfactory.

Although this readily decreased in-hospital mortality for patients with acute uncomplicated type B dissection, the long-term consequences for such a strategy were not benign, with as high as 40% progression to aneurysmal degeneration of the outer wall of the false lumen at a mean of 18 months⁶. Recent studies have shown favourable 1-year survival with medical therapy alone over historical outcome of open repair; however, this focus on 1-year survival has likely exaggerated the benefits of medical management as the primary late complication usually appears after this time frame⁸.

The recent Food and Drug Administration (FDA) approval of thoracic stent grafting for the treatment of aortic dissection has opened a new era in the treatment of type B dissections. The FDA and the Society for Vascular Surgery have partnered to gather prospective data with 5-year follow-up of thoracic endovascular aortic repair (TEVAR) treatment. This has created

an opportune time to re-evaluate the natural history of the medically managed dissected aorta. But the optimal management of these Dissections and the need for TEVAR in all patients or specific subset of patients still remains a matter of debate. With regard to our study the following parameter were observed and the analysis is done.

The mean age of our study subjects was 57.51 ± 10.57 years. **Christopher A. Durham et al** in their study observed that the mean age of the study subjects was 65.9 ± 15.0 years⁶. The younger age at presentation may be due to higher prevalence of hypertension in the 50 to 60yrs age group as shown in studies by Sivasubramanian et al¹⁸. As hypertension is a known risk factor for type B dissection it can be implied that compared to western populations we have a younger age at presentation in our population. The male: female ratio in the current study was 3.71:1. Similar to western populations there was a male predominance⁶. When analysing the comorbidities similar to western studies there was high prevalence of hypertension in the patients which was reported among 93.94% study subjects. **Christopher A. Durham et al** in their study observed that Hypertension was the most common risk factor and was present in 72.5% of patients⁶. Hypertension being an important risk factor for development of dissection it was found in majority of the patient population. In regard to the those with chronic kidney disease most of them had an associated hypertension or diabetes which may lead to postulation that CKD was a complication of the hypertension and diabetes. Otaki et al in their study on the impact of Chronic kidney disease on aortic disease related mortality, they found a statistically increased aortic related mortality similar to what was seen in our study¹⁹. We observed that majority of the study subjects were on single anti-hypertensive drug (48.48%). The requirement of single anti-hypertensive in less than 50% of the patients means many require more number of antihypertensive drugs for optimal blood pressure control. Early initiation of antihypertensives and optimal blood pressure controls are the pillars of the management in the acute phase of the disease⁵. As blood pressure control is a long term exercise compliance is very important in this population.

We observed 12.12% mortality among the study subjects. **Christopher A. Durham et al** in their study observed mortality among 5% study subjects, whereas they observed early failure among 12.4% study subjects. Medical therapy became the standard of care for uncomplicated acute type B aortic dissection because of its improved survival over open aortic replacement that is sustained at 1 year⁶. However, **DeBakey et al** demonstrated in 1982 an overall survival only slightly higher than 50% after 5 years⁷.

Various factors were studied for mortality in this study. The comorbidities hypertension, COPD, CKD were studied and proportion of mortality was calculated. There was no significant difference observed in mortality among those who suffered from hypertension and COPD. Mortality was found to be higher in cases who suffered from CKD. The higher mortality in the CKD explained in view of the greater cardiac risk factors in this group during the course of follow-up. In the study done by Xiao et al it was found that pre-existing CKD was a predictor for aorta related and overall mortality. With regard to the cardiovascular status, those with pre-existing cardiac disease and poor Ejection fraction was evaluated and noted that 100% mortality was observed in EF less than or equal to 60 but it was insignificant statistically as 62.07% cases alive also had EF less than or equal to 60. No significant difference observed in EF more than 60. This can be explained as those patients with poor cardiac function have greater overall mortality as seen in other studies done by Xiao et al.

With regard to the imaging findings, the mean aortic diameter was found to be larger in the group with mortality compared to those who survived. This finding is collaborated in various studies that show faster rate of progression correlates with greater aorta related mortality. Data from IRAD reveal 3-year survival of medically managed patients discharged alive after hospitalization for acute type B dissection to be only 78%¹¹. The geometry and the type of true lumen did not correlate with the mortality. An important aspect of management of Type B dissection has been the concept of aortic remodelling. Aortic remodelling is the term used to signify that there is no further blood flow into the false lumen with complete thrombosis of the false lumen and the morphological changes that occur in the aorta that reduce the subsequent risk of rupture and prevent further expansion. A common aim of all type B dissections has been to achieve false lumen thrombosis. Among mortality, 25% subjects had false lumen expansion, 50% had partial thrombosis. The absence of complete thrombosis of the false lumen implying that complete positive remodelling did not occur in these patients.

While among alive subjects 24.13% had near total to complete thrombosis, 48.27% had partial thrombosis, 17.24% had minimal thrombosis, and 6.89% had false lumen expansion. Based on the statistics seen it was seen that mortality was correlated with poorer remodelling as survival was often correlated with complete thrombosis. In a similar study done by Patterson et al, they noticed a complete obliteration of false lumen thrombosis was achieved in medically managed group. In our study group, though small with optimal blood pressure management we managed to achieve complete thrombosis in 24.13% of patients without intervention, higher

than INSTEAD trial which had 19.4% at 2 years follow up with best medical therapy. Though TEVAR was found to have higher rate of false lumen thrombosis in INSTEAD study, it did not show a statistical difference in overall mortality¹¹. True lumen expansion and reduction in the false lumen was seen more commonly in the survivors.

An important finding in our study was the size of the entry tear size a predictor of mortality. Even though there was no statistical significance, it was observed that patients with larger entry tear had higher mortality. Evangelista A et al in their study found that entry tear size more than 10mm in size predicted a poor prognosis²⁰. The theory behind this is the assumption that larger entry tear leads to greater pressurization of the false lumen contributing to its expansion. Luebke et al in their review of prognostic markers of patients with Type B dissection, they found that tears located within 5cm of Left subclavian artery along with large size of entry tears with uncontrolled hypertension were predictive of poor outcomes²¹. Also noticed that factors which were predictive of good prognosis and survival include true lumen expansion and false lumen thrombosis and complete obliteration of false lumen. These findings were also noticed in our study group, which showed survival associated with smaller entry tears with complete false lumen thrombosis or partial thrombosis and expansion of true lumen. In our study it was seen that mortality occurred when the size of the entry tear was greater than 16mm and another important aspect seen was in the patients surviving more than 5years the mean entry size diameter was less than 10mm.

In our study, it was observed that along with the false lumen characters the patient comorbidities also play an important role in the overall prognosis of these patients. This can be best illustrated even in this small study group it was observed CKD was an important predictor of mortality. It can be implied the prognosis and progression of the disease is multifactorial.

8. CONCLUSION

Based on the analysis of the outcomes it was seen that ~~although~~ majority of the patients though on conservative management had good long-term survival. Poor prognosis and mortality risk was significant in patients of CKD and poor compliance. It was also observed that there was trend of better long term survival in those patients with smaller entry tears and a trend of better radiological signs of remodelling on interval imaging was seen correlating with survival.

A corollary with this finding could be those patients with CKD, large entry tears and poorly compliant patients with uncontrolled hypertension with imaging showing no signs of remodelling may be candidates for more intensive follow up or earlier intervention.

Excluding the above high risk group the study showed good percentage of patients surviving beyond 5 years of presentation with conservative management alone. This begs the question whether the role of TEVAR should be more selective than elective. Further studies are needed with regard to this to further define the optimal management of Type B aortic dissection patients and the selective role of TEVAR to be better defined.

9. LIMITATIONS

1. As it is a retrospective study there may be a chance of potential biases and the results may be affected by confounding variables which are unmeasured and detection biases.
2. The smaller size of our patient study.

10. REFERENCES

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11. ANNEXURES

APPENDIX A: Technical Advisory Committee Report



Technical Advisory Committee (Clinical Studies)
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

Date: 28.08.2020

TAC Registration No: SCT-/S/2020/1091

Project title: OUTCOME OF MEDICALLY MANAGED UNCOMPLICATED ACUTE TYPE B AORTIC DISSECTION
SINGLE CENTER RETROSPECTIVE ANALYSIS

| | |
|--|------------------------------------|
| Principal Investigator: | |
| Dr. Sriram Manchikanti, Senior Resident, Division of Vascular Surgery, Department of CVTS, SCTIMST | |
| Degree: MBBS, MS | |
| Co-Principal Investigator(s): | |
| Dr Varghese T Panicker, Additional Professor, Department of CVTS, SCTIMST | Degree: MS .Mch CVTS |
| Dr.P. Shivanesan Assistant Professor, Department of CVTS, SCTIMST | Degree- MS .Mch (Vascular surgery) |

Members who participated in the TAC meeting on 20/06/2020

Dr Harikrishnan S (Chairman)
Dr Manikandan S
Dr Narayanan Namboodiri
Dr Jayadevan E R
Dr Sylaja P N
Dr Ramshekhar N Menon
Dr Unnikrishnan K P
Dr Syam K
Dr Sanjay G
Dr Deepti A N
Dr Sabarinath Menon
Dr Jayanand Sudhir B
Dr Srinivas G (Member Secretary)

Dr Sabarinath Menon, Dr Ramshekhar N Menon, Dr Sylaja P N, Dr Deepti A N, Dr Manikandan S, Dr Narayanan Namboodiri, Dr Srinivas G, Dr Sanjay G, Dr Harikrishnan S, Dr Unnikrishnan K P, Dr Syam K and Dr Jayadevan E R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#1072,1087, 1089, 1092, 1093, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1107, 1108, 1111, 1113, 1114, 1116, 1118, 1119, 1120, 1121, 1122, 1123, 1127, 1129, 1130)

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

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

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.

Dr Srinivas G

MEMBER SECRETARY
TAC (Clinical Studies)
SCTIMST

Note for IEC

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

APPENDIX B: ETHICS COMMITTEE APPROVAL



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee (IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1910/AUGUST/2022

12.08.2022

Dr. Sriram Manchikanti
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Sriram Manchikanti,

The Institutional Ethics Committee held on 6th August, 2022, reviewed and discussed your application to conduct the study titled "OUTCOME OF MEDICALLY MANAGED UNCOMPLICATED ACUTE TYPE B AORTIC DISSECTION- A SINGLE CENTER RETROSPECTIVE ANALYSIS" (IEC/1910).

The following members of the Ethics Sub-committee were present at the meeting held on 6th August, 2022.

| SL. No. | Member Name | Highest Degree | Gender | Scientific /Non Scientific | Affiliation with Institution(s) |
|---------|---------------------------------|-------------------------|--------|--|---------------------------------|
| 1. | Prof. Kala Kesavan P | MBBS,MD | Female | Basic Medical Scientist | No |
| 2. | Dr. Pradeep S | MBBS, MD | Male | Basic Medical Scientist | No |
| 3. | Smt. Sathi Nair | MA (English Literature) | Female | Lay Person | No |
| 4. | Dr. Christina George | MD Psychiatry | Female | Clinician | No |
| 5. | Adv. N Anand | BAL, L.LB | Male | Legal Expert | No |
| 6. | Dr. Rejnish Kumar | MBBS,MD, DNB | Male | Clinician | No |
| 7. | Prof. Narayanan Namboodiri. K K | MBBS,MD,DM | Male | Clinician | Yes |
| 8. | Dr. Srinivas G | PhD | Male | Basic Medical Scientist (Member Secretary) | Yes |

The following documents were reviewed:

1. Checklist Form
2. Declaration form
3. Covering letter addressed to the Chairman, IEC, SCTIMST
4. Forwarding letter from HOD
5. IEC Application Form
6. Study Proposal
7. TAC Approval Letter
8. Proforma
9. CV of PI and Co-PIs
10. Declaration form

IEC Decision

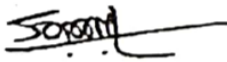
The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,



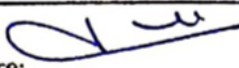
Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM



APPENDIX C: CV OF Dr. SRIRAM MANCHIKANTI

Format for CV of the Investigators

| | | | | |
|--|-------------------------------|------------|--|-------------|
| MANCHIKANTI | | SRIRAM. | | |
| Last Name | | First Name | | Middle Name |
| Date of Birth (dd/mm/yy) 26.10.1992. | | | Sex Male. | |
| Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) | | | | |
| Professional Mailing Address (Include Institution name) | | | Study Site Address (Include Institution name) | |
| Dept of CVTS (Division of Vascular surgery) SCTIMST Trivandrum 695011 | | | Dept of CVTS. SCTIMST Trivandrum 695011 | |
| Telephone (Office): 0471 2524553 | | | Mobile Number: 9915364531 | |
| Telephone (Residence): | | | Email Srirammanchikanti.m@gmail.com | |
| Academic Qualifications (Most recent qualification first) | | | | |
| Degree/Certificate | | Year | Institution, Country | |
| MS | | 2019 | PGIMER, Chandigarh | |
| MBBS. | | 2016 | IIMC, Manipal. | |
| Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration) | | | | |
| | | | TCMC 74199 | |
| Current and previous positions (most recent position first) | | | | |
| Month and Year | Title | | Institution/Company, Country | |
| 2020 - | Vch Vascular Surgery Resident | | SCTIMST. | |
| Brief summary of relevant research experience: | | | | |
| Current project/s at hand: | | | | |
| Signature:  | | | Date: Place: | |


APPENDIX D: CV OF Dr. P. SHIVANESAN

Format for CV of the Investigators

| | | | |
|---|----------------|--|-------------|
| PITCHAI | | SHIVANESAN | |
| Last Name | | First Name | Middle Name |
| Date of Birth (dd/mm/yy) 14/8/1985 | | Sex MALE | |
| Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) CO-INVESTIGATOR | | | |
| Professional Mailing Address (Include Institution name) | | Study Site Address (Include Institution name) | |
| Dept of CVTS SCTIMST, Trivandrum | | Dept of CVTS, SCTIMST, Trivandrum | |
| Telephone (Office) | | Mobile Number 7012704425 | |
| Telephone (Residence) | | Email drpshivanesan@gmail.com | |
| Academic Qualifications (Most recent qualification first) | | | |
| Degree/Certificate | Year | Institution/Country | |
| MCh VASCULAR SURGERY | 2017 | SCTIMST, Trivandrum | |
| MS Gen Surgery | 2012 | PRIMER, Choddygoh | |
| Details of professional registration (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of) | | | |
| TCMC 64489 | | | |
| Current and previous positions (most recent position first) | | | |
| Month and Year | Title | Institution/Company, Country | |
| 2017 | Asst Professor | SCTIMST, Trivandrum | |
| Brief summary of relevant research experience: | | | |
| Current project/s at hand: | | | |
| Signature: P. Shivanesan | | Date: Place: Trivandrum | |

APPENDIX E: CV OF Dr. VARGHESE T. PANICKER

Format for CV of the Investigators

| | | | |
|---|-----------------|--|-------------|
| T. PANICKER | | VARGHESE | |
| Last Name | | First Name | Middle Name |
| Date of Birth (dd/mm/yy) 29/05/1973 | | Sex M | |
| Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) | | | |
| Professional Mailing Address (Include Institution name) | | Study Site Address (Include Institution name) | |
| DEPT. OF CVTS SCTIMST, TRIVANDRUM-695011 | | DEPT. OF CVTS SCTIMST, TRIVANDRUM-695011 | |
| Telephone (Office): 0471-254 553 | | Mobile Number: 93878 01642 | |
| Telephone (Residence): | | Email VTP @ SCTimst. ac.in | |
| Academic Qualifications (Most recent qualification first) | | | |
| Degree/Certificate | Year | Institution, Country | |
| MBS | 1997 | MCH, TRIVANDRUM | |
| MS | 2004 | MCH, TRIVANDRUM | |
| MCh | 2008 | SCTIMST, TRIVANDRUM | |
| Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration) PCMC 27238 | | | |
| Current and previous positions (most recent position first) | | | |
| Month and Year | Title | Institution/Company, Country | |
| 2015 | Asst. Professor | SCTIMST, Trivandrum. | |
| Brief summary of relevant research experience: | | | |
| Current project/s at hand: | | | |
| Signature:  | | Date: Trivandrum Place: 21/01/2019 | |

APPENDIX F: PLAGIARISM SCAN REPORT





PLAGIARISM SCAN REPORT

Date July 24, 2022

Exclude URL: NO



Unique Content **92%**

Plagiarized Content **8%**

Paraphrased Plagiarism **0**

Word Count 1,393

Records Found 3

CONTENT CHECKED FOR PLAGIARISM:

Aortic dissection occurs in 4 or 5 persons per 100,000 annually, making it the most common aortic emergency. Furthermore, 20% to 30% of patients affected die before hospital admission. Although substantial improvements have been made since Morris et al reported the first successful repair in 1963¹, immediate surgical correction has been relatively static dogma for the treatment of acute type A aortic dissection. Consensus for the treatment of type B aortic dissection, however, has been more dynamic.

Early attempts at repair of acute type B dissection included decompression of the false lumen by creation of distal re-entry in the iliac artery, cellophane wrapping, and intimal tear excision and aortic replacement¹. However, mortality with these strategies was markedly high, prompting Palmer and Wheat to introduce medical management focused on lowering systolic blood pressure and pulse as the standard of care.

Medical management with anti-impulse therapy has remained the preferred treatment option for uncomplicated acute type B dissection, with in-hospital mortality rates typically <10> Although interventional therapies may struggle to improve on medical management in the acute setting, when one examines longer term follow-up data, the results of medical management are less satisfactory.

Although this readily decreased in-hospital mortality for patients with acute uncomplicated type B dissection, the long-term consequences for such a strategy were not benign, with as high as 40% progression to aneurysmal degeneration of the outer wall of the false lumen at a mean of 18 months⁶. Recent studies have shown favourable 1-year survival with medical therapy alone over



PLAGIARISM SCAN REPORT

Date July 24, 2022

Exclude URL: NO



Unique Content **99%**

Plagiarized Content **1%**

Paraphrased Plagiarism **0**

Word Count 993

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CONTENT CHECKED FOR PLAGIARISM:

Type B dissections are those where the tear begins distal to the left subclavian artery and they commonly occur in the descending thoracic aorta.¹ The incidence of aortic dissection is 5 to 30 cases per 1 million people per year² making it relatively rare.

The mean age of presentation of Type B aortic dissection occurs between 50-65 years. Patients in the 3rd and 4th decade of life have commonly associated connective tissue disorders including Marfan`s and Ehler-Danlos syndrome.³ The most common risk factors associated with the development of aortic dissection is uncontrolled hypertension. The most common presentation of Type B dissection is chest pain and back pain. After the diagnosis of dissection is made the management of Type B dissection varies from the predominant surgical management of type A dissection . The type B dissections are classified as either uncomplicated or complicated to further help in the management of these patients. Complicated Type B dissections refer to aortic rupture, visceral or renal ischemia, lower extremities ischemia, or spinal cord ischemia (SCI). The expansion to the aortic arch or proximal descending aorta with total diameter of 4.5 cm or greater is also considered a complicated dissection.⁴ Absence of these features is called uncomplicated dissection. The duration of symptoms is also important with acute dissections defined as those less than 14 days of durations and occurring beyond 3 months are called chronic Type B dissections. Management of acute uncomplicated type B dissections is initially medical consisting of sufficient pain control and reduction of the systolic blood pressure to less than 120 mm Hg or to the lowest level necessary to maintain vital functions. ⁵ The management in chronic dissections is based on maximum thoracic aortic diameter. Those with diameters greater than 5.5 cm or a documented