A COMPARATIVE STUDY OF COST BENEFIT ANALYSIS BETWEEN BRONCHIAL ARTERY EMBOLIZATION AND CONSERVATIVE MANAGEMENT OF HEMOPTYSIS IN PULMONARY TUBERCULOSIS PATIENTS

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ABSTRACT: Massive hemoptysis secondary to Pulmonary Tuberculosis patients (PTB) is associated with high mortality rate. Bronchial Artery Embolization (BAE) has emerged as the lifesaving option in the management of such patients. Surgical management is associated with high complication rates and the facility of Cardio Thoracic and vascular Surgery (CTVS) is not available in most government district and medical college hospitals. Traditionally conservative management has been the mainstay of treatment of these patients. This study was conducted to obtain the cost benefit analysis between bronchial artery embolization and conservative management of hemoptysis in PTB patients.

KEYWORDS: BAE, Massive Hemoptysis, Pulmonary Tuberculosis.

INTRODUCTION: Pulmonary Tuberculosis is as old as history of mankind and complication of hemoptysis in such patients is equally well known and documented. Hemoptysis at times becomes massive and warrants emergency medical attention.

Neglected or untreated hemoptysis accounts for up to 80% mortality. In India due to economic constraints the cost of treatment becomes an important aspect in diseases where repeated medical attention or admission in hospital is required. Previously the treatment of massive hemoptysis was largely conservative and in some case surgical options were the remedies available.

Surgical expertise again to carry out such skilled surgeries is scarcely available. With the advent and availability of Bronchial artery embolization facilities mortality and morbidity was significantly reduced and their visits to hospital and stay in the hospital was also minimized.

In view of the this observation the study to compare the cost benefit analysis between bronchial artery embolization and conservative management of hemoptysis in Pulmonary Tuberculosis patients was carried out and the results were in favor of test group of patients who were treated through Bronchial Artery Embolization using gel foam particles.

Massive hemoptysis is a common complication of pulmonary tuberculosis is associated with approximately 80% mortality in neglected or untreated patients.¹ Bronchial Artery Embolization (BAE) is an established procedure for control of hemoptysis and is effective in up to 90% cases.² The other definitive alternative is surgical therapy which is associated with high mortality and morbidity.³

Big Void of Cardio-Thoracic infrastructure and skilled manpower is also a major limitation in using surgical therapy. The study was conducted to test the cost benefit of BAE in patients from massive hemoptysis/ recurrent small intractable hemoptysis patients attending to or referred to medical college Jabalpur.
Of the various complications of tuberculosis massive hemoptysis is a very common frightening and life threatening complication. It is important to recognize massive hemoptysis quickly, because without urgent treatment, up to 80% of patients may die.\textsuperscript{4,5}

Unlike hemorrhage in other areas of the body, the primary cause of death from pulmonary hemorrhage is most commonly asphyxiation rather than exsanguination. Given the limited capacity for the lung to preserve oxygen transfer in the setting of massive hemoptysis, a rapid and effective method for controlling hemorrhage is essential to minimize death in patients demonstrating respiratory compromise.

Massive hemoptysis is defined as the expectoration of more than 300 ml of blood in a 24-hour period.\textsuperscript{6}

**MATERIALS AND METHODS:** The present study was a retrospective study involving pulmonary Tuberculosis patients who presented with Massive hemoptysis or recurrent hemoptysis. The study was conducted in the department of Pulmonary and Sleep Medicine Department and Department of Radiodiagnosis of NSCB Medical College Jabalpur. Apart from routine investigations like HBS Ag, HIV BT CT PT/INR whenever indicated higher investigations like Computerized Tomography scan with contrast studies and Fiberoptic Bronchoscopy was done.

Between January 2009 and December 2010 prior to availability of BAE facility in the institute forty cases treated on conservative therapy were used as control. After January 2011 forty cases managed by BAE were included as test cases.

**CRITERIA:**

**Inclusion Criteria:**
- Massive hemoptysis more than 300 ml in 24 hrs.
- Recurrent bouts of moderate hemorrhage (three or more bouts of 100 ml of blood per day within a week).

**Exclusion Criteria:**
- Pregnant and/or lactating women.
- Traumatic hemoptysis.

Test group was treated by BAE. Chest x-ray was done in all cases to identify any acute radiographic changes in the lung fields, localize the site of bleeding, and discover other potential causes of bleeding, such as a foreign body or cavity with mycetoma.

If no localizing signs were present. Bronchoscopy was done to localize the site of bleeding. Patients who had undergone previous bronchial artery remobilization procedures were not excluded from additional remobilization procedures. Bleeding in such cases was thought to arise from recanalized vessels or hypertrophied non-bronchial systemic collaterals.

Prior to the procedure, a brief clinical and neurological examination, HIV, HBsAg status, PT/INR and serum creatinine was done.

On the day prior to the procedure a consent form issued to the patient and his relatives in the language they were able to understand was given to take an informed consent.

For the procedure patient is shifted to the angio suite and usually the right femoral artery was accessed.
A preliminary descending thoracic aortogram is performed as a roadmap to the bronchial arteries. Five or six French sheaths are commonly used, through which selective catheters like sim 1 or 2, cobra. Head hunter and shepherd crook are placed.

Typically 4, 5, or 5.5 Fr catheters are routinely used. After cannulation of the ostium of vessel micro catheter with a large inner lumen like progreat terrumo was used for super selective cannulation of the bronchial arteries and contrast injected. Tanaka et al\(^7\) demonstrated the value of super selective catheterization with a micro catheter. They documented improved hemorrhage control when using super selective versus selective catheterization techniques.

Abnormal angiographic appearances that supported site of bleeding included tortuosity, hypertrophy, hyper vascularity, aneurysms, extravasation, and bronchial artery to pulmonary artery or vein shunting. Embolization was carried out till stasis of flow was noted.

Gel foam being cheaper and affordable in government hospital was used for embolization. The cost of one procedure was INR 30000 including the cost of support consumables so due to this limitation catheters were reused after sterilization in about five to six patients to reduce the cost to approximately INR 5000 per patient.

The cost of sickness day of INR 350 was calculated from loss of daily wages due to sickness at the rate of INR 350 per day (INR 210 per day derived from per capita income of INR 74920 per annum and INR (140) for personal expenses of patient and one attendant which provides for their meals and other routine daily needs.\(^8\)

Control group was treated conservatively by correctly positioning the patient, establishing a patent airway, ensuring adequate gas exchange and cardiovascular function, and controlling the bleeding.\(^9\)

**COMPLICATIONS:** Spinal cord ischemia is the most feared and recognized complication of BAE. Fortunately serious complications were nil and minor complications like small bleed on day one after embolization and fever were noted which were easily negotiated by bed rest, reassurance and symptomatic treatment.

The cost of outpatient treatment, various pathological biochemical and radiological and other tests and inpatient treatment was calculated on the basis of fixed charges by the government hospital and cost of consultation and procedure bed charges and nursing were not considered as the same was made available free of cost to all patients. Economic burden of both the test and control group were assessed on the overall cost that was involved in the final outcome.

The various attributes that were analyzed included average number of sick days when patient had to seek medical help or was unable to carry out his normal life including the normal daily wages earning activities, loss of wages when attending or admitted in hospital during treatment or during follow up, cost of investigation, cost of medicines cost of BAE procedure including the cost of consumables like catheter used in the procedure.

Overall expenditure was calculated and in both test and control groups and then cost per patient was figured out in both groups.Causes of hemoptysis and morbidity and mortality data was also taken in account in conclusion.
Observations:

| Test Group Treated by BAE (n=40) | units | cost in INR |
|----------------------------------|-------|-------------|
| Average Number of sickness days (3) for all patients (120 days) X Average cost per sickness day @INR 350 per day | 120 X 350 | 42000 |
| Average Number of days as inpatient for all patients (120) X Average cost per inpatient day@INR 2000 | 120 X 2000 | 240000 |
| total number follow up visits for all patients (n=20) X per visit cost of follow up visits @350 | 20 X 350 | 7000 |
| Cost of basic Investigations needed to assess and treat the patients @INR1000 (CXR CBC ESR BT CT PT/INR HBSAg HIV I and II Blood Sugar) | 1000 X 40 | 40000 |
| Number of patients who needed Fiber optic Bronchoscopy (n=10) X cost of Fiber optic Bronchoscopy @INR1500 per patient | 10 X 1500 | 15000 |
| Cost of treatment /cost of BAE procedure including reusable catheter and other consumable accessory charges per patient @INR 5000 per patient | 5000 X 40 | 200000 |
| **Total Cost for all patients in INR** | | **544000** |
| **Total Cost per patient in INR** | | **13600** |

**Table 1: Showing Cost expenditure in Test group in various heads**

| Control Group Treated by conservative method (n=40) | units | cost in INR |
|----------------------------------------------------|-------|-------------|
| Average Number of sickness days (12) for all 40 patients (n=480) X Average cost per sickness day @INR 350 | 480 X 350 | 168000 |
| Average Number of days (10) as inpatient for all 40 patients (n=400) X Average cost per inpatient day@ INR 2000 | 400 X 2000 | 800000 |
| Average number of follow up visits (06) for all 40 patients (n=240) X per visit cost of follow up visits @350 | 240 X 350 | 84000 |
| Cost of basic Investigations needed to assess and treat all 40 patients @INR1000 (CXR CBC ESR BT CT PT/INR HBSAg HIV I and II Blood Sugar) | 1000 X 40 | 40000 |
| Number of patients (25) who needed Fiber optic Bronchoscopy (n=25) X cost of Fiber optic Bronchoscopy @INR1500 per patient | 25 X 1500 | 37500 |
| Cost of conservative treatment excluding inpatient included in inpatient treatment | - | - |
| **Total Cost for all patients** | | **1129500** |
| **Total Cost per patient** | | **28237.50** |

**Table 2: Showing Cost expenditure in Control group in various heads**
Group | Test Group (treated by BAE) n=40 | Control group (treated by conservative method) n=40 | Test: control Ratio
---|---|---|---
Total cost in INR | 544000 | 1129500 | 0.4816
Cost per patient in INR | 13600 | 28237.50 | 0.4816

Table 3: Showing comparison of final outcome of cost in Test and Control Group

| Description | Test Group (treated by BAE) n=40 | Control group (treated by conservative method) n=40 |
|-------------|----------------------------------|-----------------------------------------------|
| TB infection/Infiltration | 07 | 06 |
| Fibro Cavitary Disease | 18 | 19 |
| Bronchiectasis | 12 | 14 |
| Cavity with Fungal Infection /Aspergilloma | 2 | 1 |
| Malignancy | 1 | 1 |
| Others | 0 | 0 |

Table 4: Showing causes of hemoptysis in Test and Control groups

| Group | Test Group (treated by BAE) n=40 % | Control group (treated by conservative method) n=40 % |
|-------|-----------------------------------|-----------------------------------------------|
| Morbidity/complications after completion of treatment in one year | 2 | 5 | 21 | 52.5 |
| Mortality nil in one year | Nil | 1 |

Table 5: Showing Comparison of final outcome in Test and Control Group

| Group | Test Group (treated by BAE) n=40 % | Control group (treated by conservative method) n=40 % |
|-------|-----------------------------------|-----------------------------------------------|
| Fever | 4 | 10 | 7 | 17.5 |
| Re-bleeding in six months of follow up | 3 | 7.5 | 16 | 40 |
| Neurological complications | 0 | 0 | 0 | 0 |
| Renal Failure | 0 | 0 | 0 | 0 |
| Others like pneumothorax, lower respiratory tract infection etc. | 0 | 0 | 2 | 5 |

Table 6: Showing complication in Test and Control Group
DISCUSSIONS: The observations made in the study are self-evident. Conservative treatment of massive hemoptysis when facility for BAE or surgical therapy is not available is lifesaving in large number of case but where BAE and surgical options are available it is not only costly as compared to BAE but also has more complications and increased morbidity and mortality.

Conservative or surgical management in these patients is associated with high morbidity and mortality. Hemoptysis has a propensity to recur because ongoing inflammation causes continuous recruitment of collaterals, rendering them vulnerable to the recurrence if definite therapy is not initiated or in whom only medical management was instituted with fatal outcome in half of these patients.10

Since its introduction in 1973, bronchial artery remobilization has proven to be a safe and effective tool for the treatment of massive hemoptysis and is now considered the treatment of choice, with initial success rates ranging from 77 to 94%.11

Most of the literature regarding this technique as expected is based on data from developed countries which bear the brunt of this infection. Although PTB is effectively treated with chemotherapy in the majority of patients, 10 - 20% will develop serious complications.12

This percentage is increased substantially in our population because of the complex socio-economic circumstances together with a lack of insight into the disease that often leads to incomplete or partial treatment in a large number of patients. BAE for the control of hemoptysis is effective in around 90% of cases. Incomplete embolization is usually the reason for early re-bleeding. Ten to twenty per cent of patients will develop late re-bleeding within 1 year due to the proliferation of collateral vessels.

Repeated embolization may be attempted for early or late re-bleeding; however patients with localized lesions and adequate pulmonary function reserve should undergo surgical resection, as this is the most effective definitive therapy.13

RESULTS:
- Final cost of treatment per patient for Test group was INR 13600 as compared to INR 28237.50 and was largely in favor of test group.
- Causes of hemoptysis were comparable in both the groups.
- Complication was more in control group.

CONCLUSION: On the basis of this study it can be concluded that wherever facility for BAE is available patients with massive hemoptysis should be treated with it though where facility for surgical treatment is also available, a more comprehensive evaluation should be done before choosing the mode of treating massive hemoptysis.

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