

**Summer Training at
Bharat Serums and Vaccines Limited (BSV),
New Delhi**

**Study on Mucormycosis and Liposomal Amphotericin B Prescription for
Treatment**

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**Under the guidance of
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**MBA Pharmaceutical Management
2015-2017**



**The IIHMR University, Jaipur
2016**

CERTIFICATE

This is to certify that Vikas Sharma has undergone Summer Training in Bharat Serums and Vaccines Limited, New Delhi from 1st April to 31st May 2016.

The Candidate himself completed the project assigned to him during summer training. His approach to the project was sincere and proactive. This summer training is partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management.

We wish success in all his future endeavors.



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To whomsoever it may concern

This is to certify that **Mr. Vikas Sharma**, first year **MBA-Pharmaceutical Management** student from **Institute of Health Management Research, Jaipur, Rajasthan University**, has successfully completed his summer internship program in this organization from **01st April 2016 to 31st May 2016**. The topic of his summer internship was Study of ***"Mucormycosis and Liposomal Amphotericin B Prescription for Treatment"***.

During the duration of the internship, he has worked under our supervision and guidance and has shown a great amount of sincerity, interest and dedication in carrying out the responsibilities assigned to him.

We are satisfied with the output of his work and we wish him all the success in future.

For Bharat Serums and Vaccines Limited

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To place on record, I owe a debt of gratitude to all my teachers for grooming me and my classmates for the inspiration needed to work with dedication and motivation throughout as an Intern at Bharat Serum and Vaccines Ltd.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

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Executive Summary

The topic assigned was “A Study on Mucormycosis and Liposomal Amphotericin B prescription for treatment” with the primary objectives:

- To study the incidence of Mucormycosis.
- To identify the stages of the Mucormycosis during detection.
- To identify the preferred choice of line of treatment by doctors.
- To study the duration of treatment in terms of vials used.

The project was carried out in 3 stages:

The first stage was to study about the mucormycosis and prepare a questionnaire followed by stage two which involves meeting with the ENT specialists in various government and private hospitals and conduct the survey. After the completion of the survey, the last stage followed which includes analyzing the data and getting a conclusion.

Following findings were observed after meeting with ENT specialists:

- **Incidence of Mucormycosis**
 - Approximately 72.50% specialists observed 0-5 patients/year suffering from the Mucormycosis, which suggest that it is a rare disease.
 - Only 25% specialist observed 5-10 patients/year and 2.5% more than 15 patients/year.
 - It was also observed that majority of the patients suffering from the Mucormycosis were immune-compromised which includes underlying causes, like Diabetes, Cancer, AIDS or use of immunosuppressant agents in case of organ transplant.
- **Stages of the Mucormycosis during detection**
 - 95% of the specialists responded with observing the patients in the advanced stage which includes, Orbital Involvement, fungal sinusitis, Rhino cerebral Mucormycosis, Sinonasal etc.
 - Only 5% of the patients were detected with the disease still in the initial stage.
 - In most of the cases by the time clinical examination results confirm the Mucormycosis, it was already in an advanced stage.
- **Line of treatment**
 - Approximately 51% of the specialist responded with the Liposomal Amphotericin B being their preferred line of treatment for the Mucormycosis.
 - Approximately 36% specialists responded that either they use Liposomal Amphotericin B or Amphotericin B depending upon the affordability of the drug by patients.
 - 7.5% were found to be having Amphotericin B their preferred line of treatment for the disease.

➤ **Duration of treatment in terms of vials used**

- 35% of the specialists were found to be using an average of 30-50 vials/patient with each vial containing the 50mg drug.
- Approximately 27.50% use 50-70 vials per patient for the management of the Mucormycosis. Same no of doctors responded with using more than 70 vials per patient.
- Approximately 9% were using 20-30 vials.

This study shows that Liposomal Amphotericin B is most prescribed drug and as the incidence of Mucormycosis are increasing there is a huge market in this area.

Company Profile

Bharat Serums and Vaccines Limited (BSV) is one of the fastest growing biopharmaceuticals companies in India and have been ranked amongst the top Indian Biopharmaceutical companies. With its inception in 1971 by Dr. Gautam and Bharat Daftary, the company has 2 manufacturing units in Ambarnath, Maharashtra, 3 independent R&D facilities and a horse farm in outskirts of Maharashtra and over 900 employees.

With its 75% of business coming from domestic markets, its international business is slated to grow exponentially.

Vision

To Be an Innovative, Caring and Trustworthy Partner in Bringing Life To Life

- Mitigating the anguish and suffering of millions.
- Underlying fairness and transparency in dealings with all stakeholders including employees and business partners.
- The Group is driven by an informal culture fostering cohesion and innovation

Presence

Domestic

Products are sold through 6 specialized divisions and have over 25 brands.

- **DIVA:** prime division of BSV, operating in Gynaecology and Obstetrics segment
 - Flagship Brand: Rhoclone and Hucog
- **ASPIRE:** A complete solution in AST (Assisted reproductive Technology)
 - Flagship Brand: Foligraf
- **ELITE:** A tender division of BSV, operating in hospital-based emergency medicine and casualty
 - Flagship Brand: Tetglob, Equirab, and ASVS
- **ALTIUS:** Second largest division of the company and operating in Critical Care segment
 - Flagship Brand: Gamma IV and Albumin
- **ANAGEN:** Offering cornerstone therapies in Transplantation and Aplastic Anemia
 - Flagship Brand: Thymogam and Ampholip
- **UROCARE:** Offering cornerstone therapies in Urological problems
 - Flagship Brand: Luprodex

International

- With a zest born out of the desire to improve health and quality of life globally, BSV started its international business operations in early 2000. The international business operation got a major boost with the commissioning of the new Ambernath plant in 2003.
- The Company's products are registered in more than 45 countries and its manufacturing facilities are accredited and certified by various regulatory authorities from Asia, Latin America, Middle East, Africa , etc
- The company also has global subsidiaries namely
 - BSV BIOSCIENCES, INC (United States)
 - BSV BIOSCIENCE,GMPH (Germany)

Introduction

Background

Mucormycosis is an opportunistic infection that typically develops in patients with weakened immune systems, diabetes, kidney failure, organ transplants, or chemotherapy for cancer. Mucormycosis has emerged as the third most common invasive mycosis in terms of importance and seriousness after candidiasis and aspergillosis. It is a serious but rare fungal infection caused by a group of fungi called mucormycetes. These fungi live throughout the environment, particularly in soil and in association with decaying organic matter, such as leaves, compost piles, or rotten wood.

Fungi of the Mucorales order of the class Zygomycetes are responsible for this infection. Mucorales with 6 genera: Rhizopus, Mucor, Lichtheimia, Rhizomucor, Apophysomyces and Cunninghamella are the pathogenic organisms that produce this invasive disease in humans. Among these Rhizopus is most common genus associated with Mucormycosis. Other genera are less common.

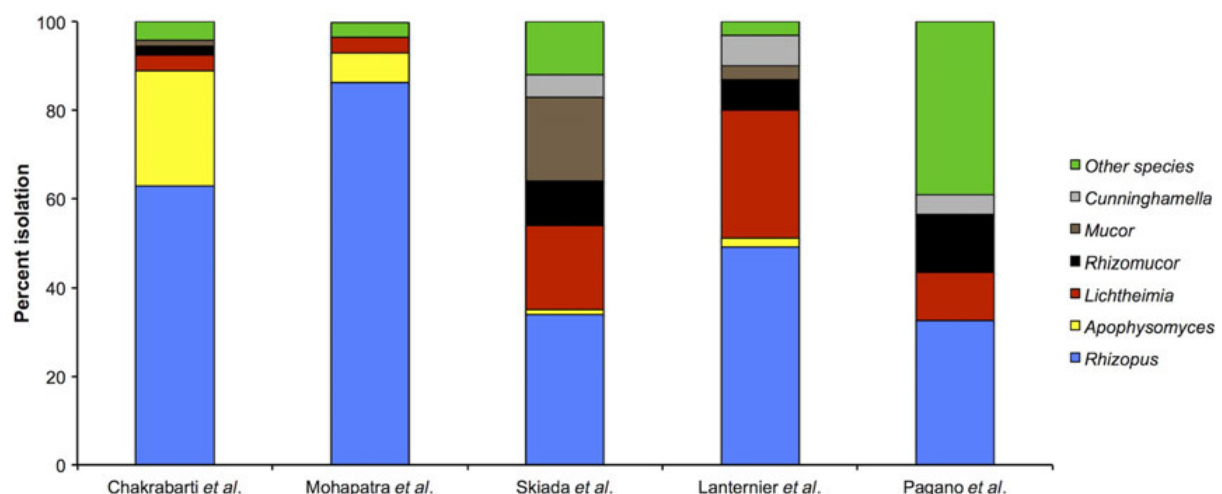


Figure 1: Agents of Mucormycosis. The data shown are from studies by Chakrabarti et al. (India), Mohapatra et al. (India), Skiada et al. (Europe), Lanternier et al. (France) and Pagano et al. (Italy)

It can occur in nearly any part of the body. It most commonly affects the sinuses or the lungs after inhaling fungal spores from the air, or the skin after the fungus enters the skin through a cut, scrape, burn, or another type of skin trauma.

Types of Mucormycosis

Based on anatomic localization, mucormycosis can be classified as:

1. **Rhinocerebral Mucormycosis** is an infection of the nose, eyes, and brain. The fungus destroys the tissue of the nasal passages, sinuses, or hard palate, producing a black or pus-filled discharge and visible patches of dying tissue. The patient will typically have a fever, pain, and forward bulging of the eyes (proptosis). The fungus

then invades the tissues around the eye socket and eventually the brain. It is the most common form of mucormycosis in patients with diabetes mellitus. It may also occur in patients with underlying malignancies, recipients of hematopoietic stem cell or solid organ transplants and individuals with other risk factors. The infection develops after inhalation of fungal sporangiospores into the paranasal sinuses.

2. **Pulmonary Mucormycosis** is the most common type of mucormycosis in people with cancer and in people who have had an organ transplant or a stem cell transplant. The overall mortality rate in patients with pulmonary mucormycosis is high (76%); it is even higher in severely immunosuppressed patients. The fungus enters the patient's lungs, where it eventually invades a major blood vessel, causing the patient to cough up blood or hemorrhage into the lungs.
3. **Gastrointestinal mucormycosis** can result from ingestion of the fungal spores. This type of mucormycosis is less common among adults and is more common among young children, especially in premature or low-birth-weight infants as well as malnourished adults. It may lead to intestinal perforation and other complications requiring immediate surgery.
4. **Cutaneous mucormycosis** occurs after the fungi enter the body through a break in the skin (for example, after surgery, a burn, or other types of skin trauma). This is the most common form of mucormycosis among people who do not have weakened immune systems. Depending on the extent of the infection, cutaneous mucormycosis is classified as localized when it affects only the skin or subcutaneous tissue; deep extension when it invades muscle, tendons, or bone; and disseminated when it involves other non-contiguous organs.
5. **Disseminated mucormycosis** occurs when the infection spreads through the bloodstream to affect another part of the body. The brain is the most commonly affected part of the body, but other organs such as the spleen, heart, and skin can also be affected. Patients with iron overload (especially those receiving deferoxamine), profound immunosuppression or profound neutropenia and active leukemia are the classic groups at risk for disseminated mucormycosis.

Treatment

Mucormycosis is a serious infection and needs to be treated as soon as possible. Treatment is usually begun without waiting for laboratory reports because of the rapid spread and high mortality rate of the disease. Therapy includes intravenous Liposomal Amphotericin B or Amphotericin B, surgical removal of infected tissue, and careful monitoring and management of the disorder or condition that is responsible for the patient's vulnerability. Most patients who survive require at least 4-6-week course of treatment with Liposomal Amphotericin B. Liposomal Amphotericin B is preferred over the Amphotericin B for the treatment as both have similar efficacy at same dose but the efficacy of Liposomal Amphotericin B can be

improved by giving a higher dose. Liposomal Amphotericin B has a less adverse effect compared to Amphotericin B and found to have extensively and rapidly distributed. Follow-up care includes educating patients about the signs of recurrent mucormycosis particularly facial swelling and a black discharge from the nose and telling them to see a doctor at once if they notice these symptoms. Patients who survive rhinocerebral mucormycosis are often left with severe facial disfigurement and usually require plastic surgery to restore their appearance.

Rationale

Mucormycosis is a rare but emerging fungal infection with a high mortality rate. The mortality rate in case of diabetes patients is 50% which rises up to 100% in case of AIDS and Cancer patients. The high mortality rate is also due to detection of the disease in late stages due to lack of awareness and inadequate diagnostic facilities. As the cases of uncontrolled diabetes are increasing in India it has become one of the most common risk factors. Other factors include immunosuppression for the purpose of organ transplant, trauma, leukemia patients etc. Increasing incidence of mucormycosis has been reported from India. It has need of the hour to take measures for early detection and providing affordable and safe treatment measures.

The study has provided insights on:

- The incidence of mucormycosis in Govt. and private hospitals.
- Stages of the detection of disease.
- Most preferred line of treatment used by specialists and reason for using that line of treatment.
- Duration of treatment in terms of dose.
- Comparison of the stages of detection and treatment measures taken in govt. and private hospitals.

Objectives

- To study the incidence of Mucormycosis.
- To identify the stages of the Mucormycosis during detection.
- To identify the preferred choice of line of treatment by doctors
- To study the duration of treatment in terms of vials used.

Methodology

Sample Design:

Descriptive study

Sampling:

Non probability convenience sampling

Sample population:

ENT Specialists in various govt. and private hospitals

Sample Size:

Respondents:80

Hospitals: 29

Sample area:

Delhi-NCR

Tool:

Questionnaire to collect primary data

Microsoft Excel for analysis

Data Collection:

Primary- Through questionnaire and meeting with respondents

Secondary- To understand study topic and objectives information from various sources like articles, journals, previous relevant studies was collected.

Study duration:

Two months

Findings and Interpretation

Objective 1: To study the incidence of Mucormycosis

It was found that 72.50% of ENT specialists examine 0-5 patients per month suffering from mucormycosis.

It was followed by 25% responses about examining 5-10 patients per month.

Only a very small number of specialists i.e. 2.5% responded about examining more than 15 patients per month.

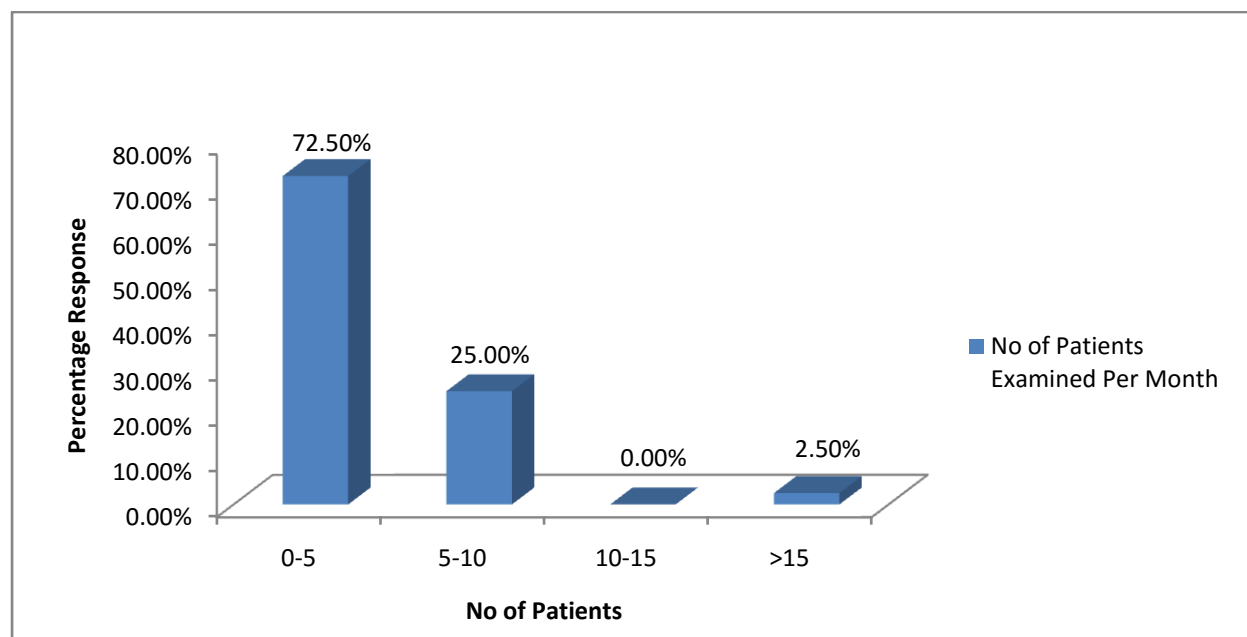


Figure 2: Total No of Patients vs Percentage Response (Per Month)

Government vs Private Hospitals

Survey was conducted among the ENT specialists of both government and private hospitals. It was found that 47.50% of the government specialists examine 0-5 patients per month suffering from mucormycosis. While in private hospitals 97.50% responded about examining 0-5 patients per month.

50% of the government hospital specialists responded that they examine 5-10 patients per month while in the case of private hospitals it was 0%.

It was also found that only 2.5% of specialists from both types of hospitals examine more than 15 patients per month.

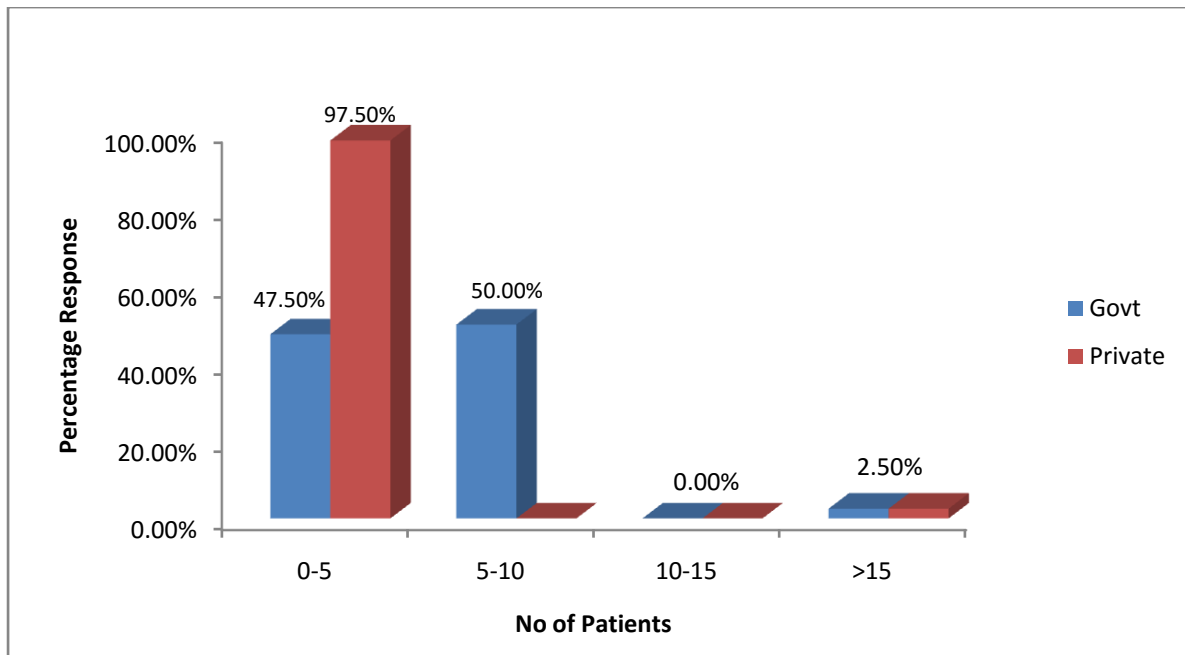


Figure 3: Total No of Patients in Government and Private Hospitals vs Percentage Response (Per Month)

Objective 2: To identify the stages of the Mucormycosis during detection.

When questioned about stages at which most of the patients get detected 95% of the specialists responded about the stages which fall into the category of the advanced stage of mucormycosis. This includes extensive stage, surgical requirement stage, Sinonasal, fungal sinusitis, invasive, orbital involvement, rhino-cerebral etc.

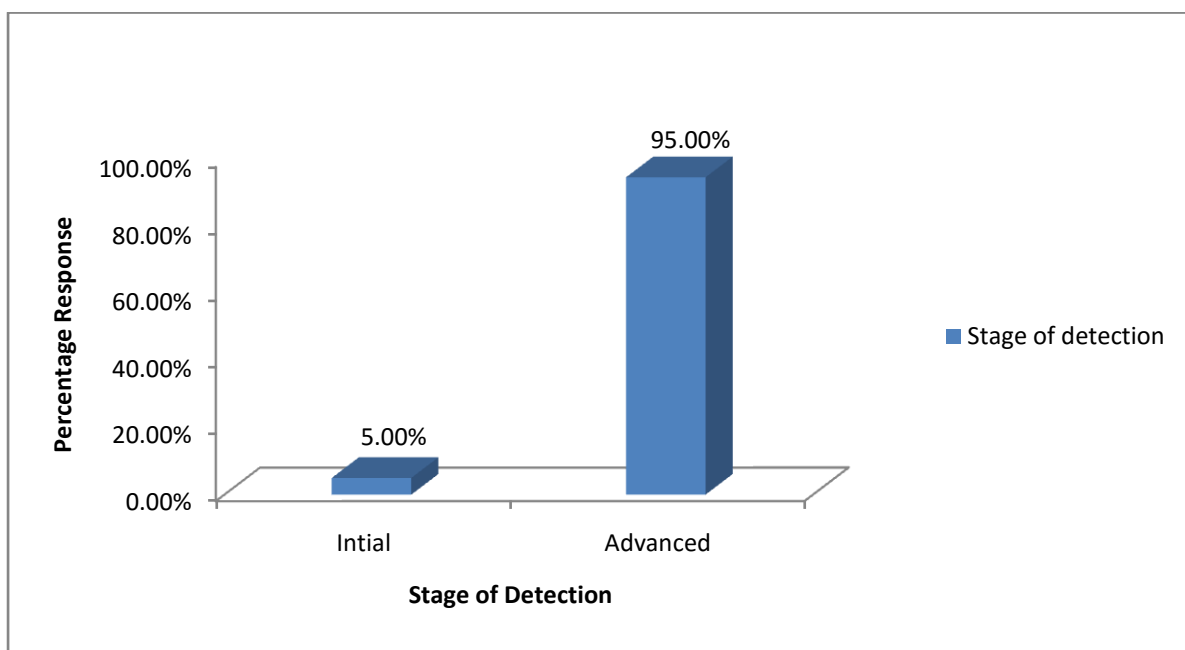


Figure 4: Stage of Detection vs Percentage Response

It was also recorded that at this stage patients require surgical debridement for the complete removal of affected part with the antifungal treatment.

Only 5% of the specialists responded about detection of disease in early or initial stages.

Government vs Private Hospitals

All government specialists i.e. 100% responded about detection of infection in the advanced stage.

90% specialists from private hospital responses were about detection of infection in the advanced stage while only 10% were about in initial stages.

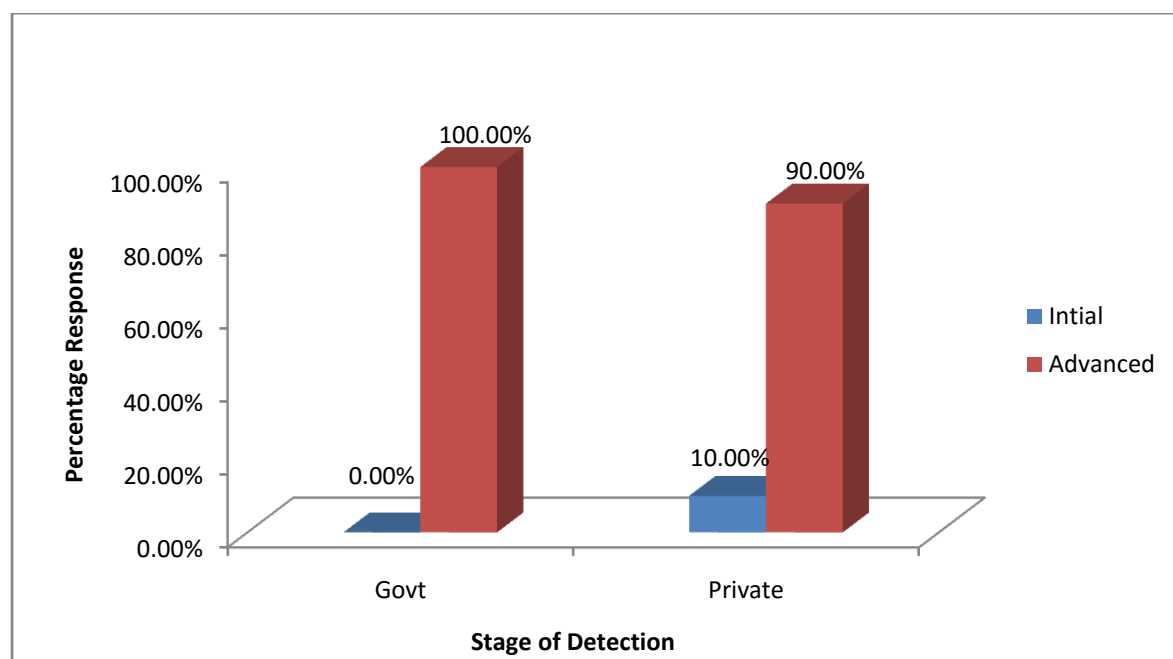


Figure 5: Stage of Detection in Government and Private Hospitals vs Percentage Response

Objective 3: To identify the preferred choice of line of treatment by doctors

1. Preferred line of treatment

It was found that approximately 51% specialists responded about Liposomal Amphotericin B (LAMB) being their preferred line of treatment for mucormycosis. The main reason given for prescribing Liposomal Amphotericin B was efficacy and less toxicity of the drug.

Followed by approximately 36% responses about either LAMB or AMB (Amphotericin B) being their line of treatment decided based on the affordability of drug by the patient.

7.5% of the total responses were about having Amphotericin B their preferred line of treatment for the management of infection.

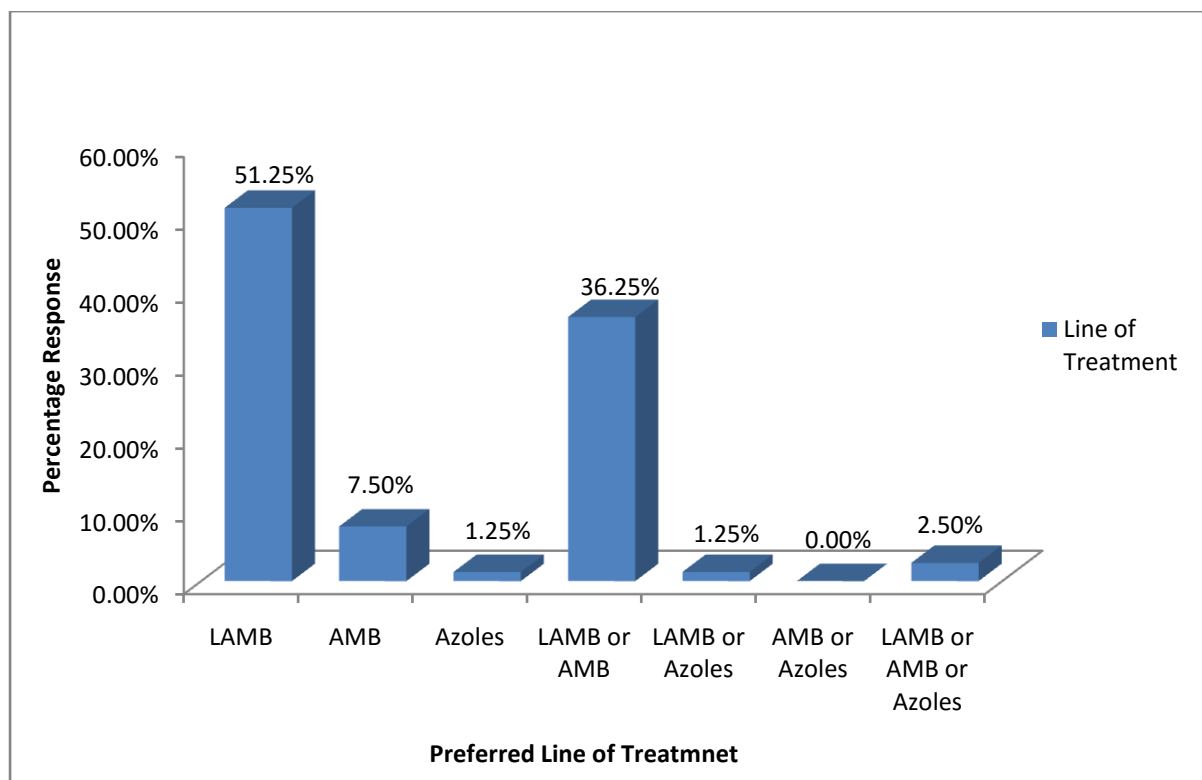


Figure 6: Preferred Line of Treatment vs Percentage Response

1.25% responses were about having Azoles their line of treatment. Similar numbers of responses were about choosing either Liposomal Amphotericin B or Azoles.

2.5% responded about using either of all three of Liposomal Amphotericin B, Amphotericin B or Azoles for the treatment.

Few of the responses about brands of these drugs available in hospital pharmacy were also received these includes; Phosome, Fungisome, Ambisome, Fungizone, Amfocare, Amphotin, Ampholin. While Azoles prescribed were Voriconazole and Posaconazole.

Government vs Private Hospitals

In the case of government hospitals, it was recorded that 42.50% has Liposomal Amphotericin B their preferred choice of line of treatment which is less in comparison to 60% of private hospital specialists.

5% of the government and 10% private hospital doctors responded having Amphotericin B their line of treatment for mucormycosis.

52.50% government doctors responded having either Liposomal Amphotericin B or Amphotericin B being their line of treatment while in the case of private specialists 20% of total responses were regarding this.

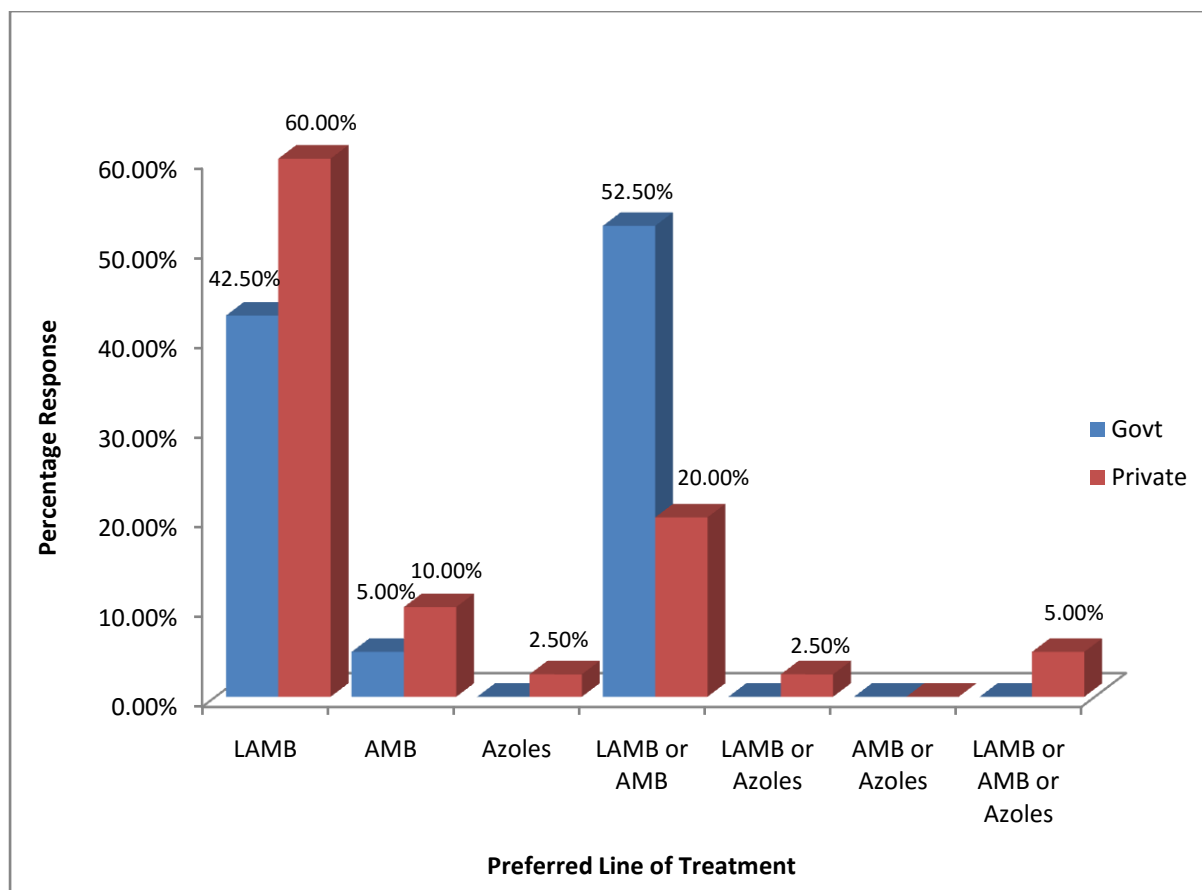


Figure 7: Preferred Line of Treatment in Government and Private Hospitals vs Percentage Response

2.5% of private specialists responded having either Liposomal Amphotericin B or Azoles their line of treatment while in the case of government doctors none of them responded same.

5% of private hospital specialists responded about using either of all three of Liposomal Amphotericin B, Amphotericin B or Azoles for the treatment.

2. Prescription for Liposomal Amphotericin B

When questioned about the numbers of patients treated with Liposomal Amphotericin B approximately 69% responded about treating 0-5 patients. Followed by 25% responses for treating 5-10 patients.

1.25% responses were about treating 10-15 and more than 15 patients with Liposomal Amphotericin B.

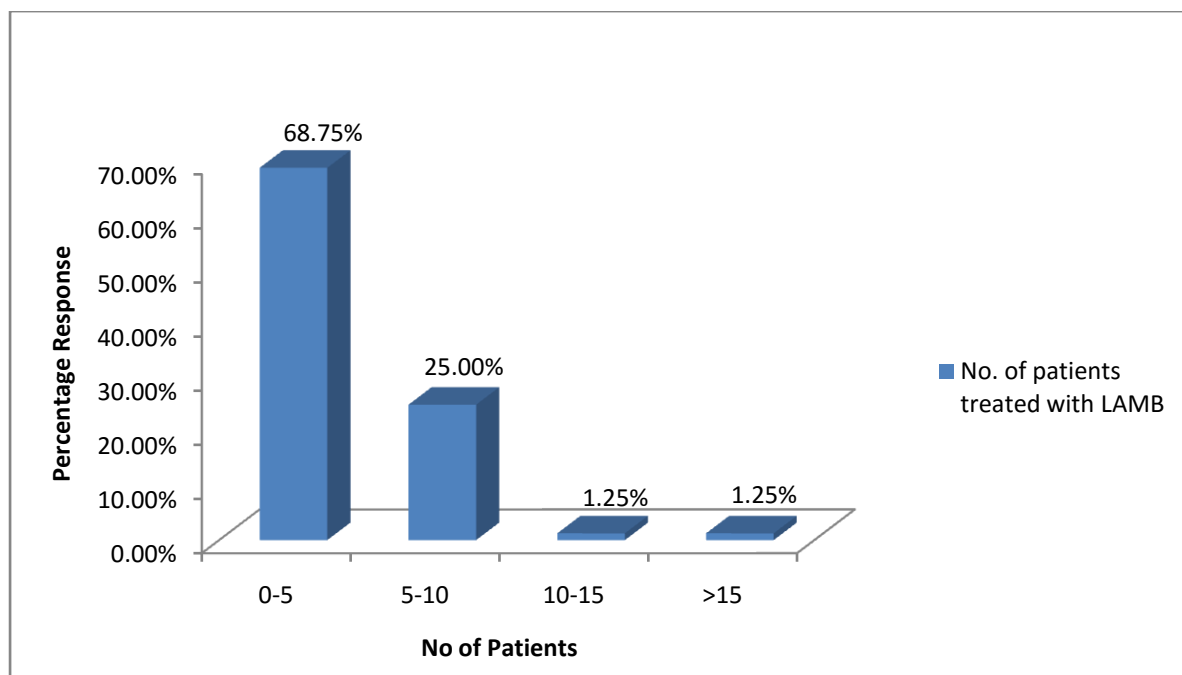


Figure 8: Total Number of Patients Treated with Liposomal Amphotericin B vs Percentage Response (Per Month)

Government vs Private Hospitals

When numbers of patients treated with Liposomal Amphotericin B were compared for government and hospital it was found that 47.50% government and 90% private specialists responded with 0-5 patients.

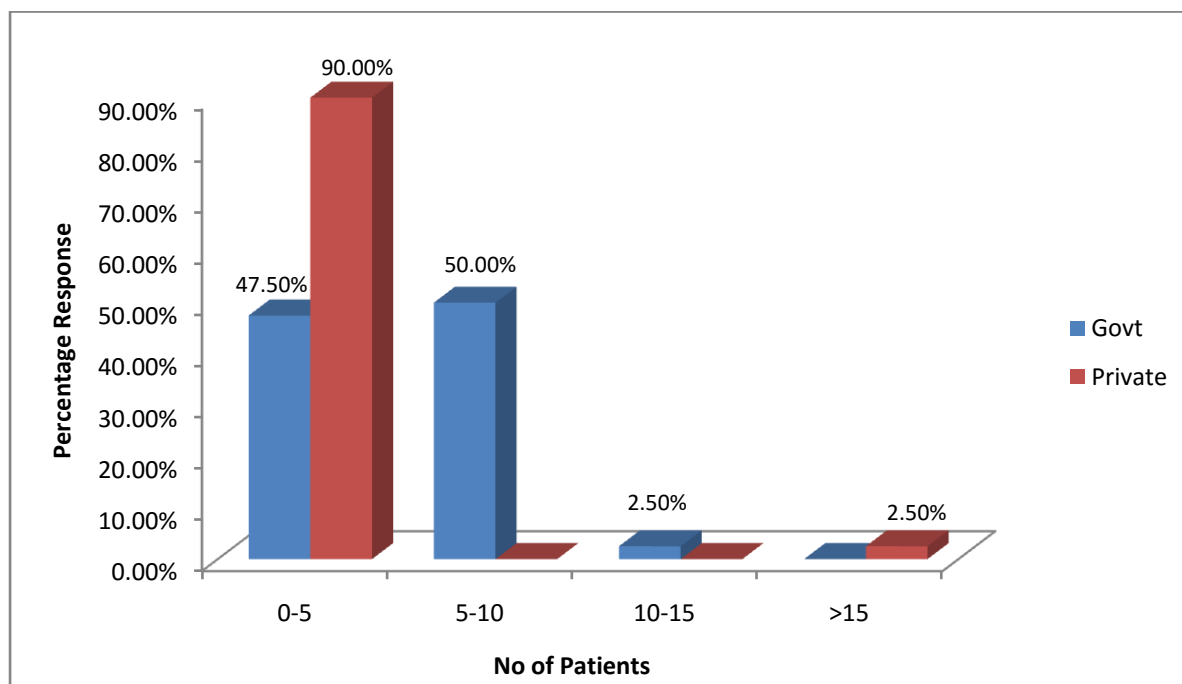


Figure 9: Total Number of Patients Treated with Liposomal Amphotericin B in Government and Private Hospitals vs Percentage Response (Per Month)

50% government specialists responded for treating 5-10 patients with Liposomal Amphotericin B while in the case of government hospitals no such response received.

2.5% responses from government specialists were for 10-15 patients.

More than 15 patients were treated with Liposomal Amphotericin B by 2.5% private hospital specialist as shown in figure 9.

3. Prescription for Amphotericin B

Approximately 41% of total doctors were found to be prescribing Amphotericin B to 0-5 patients followed by 6.25% to 5-10 patients. Only 47.50% doctors were found to be prescribing Amphotericin B.

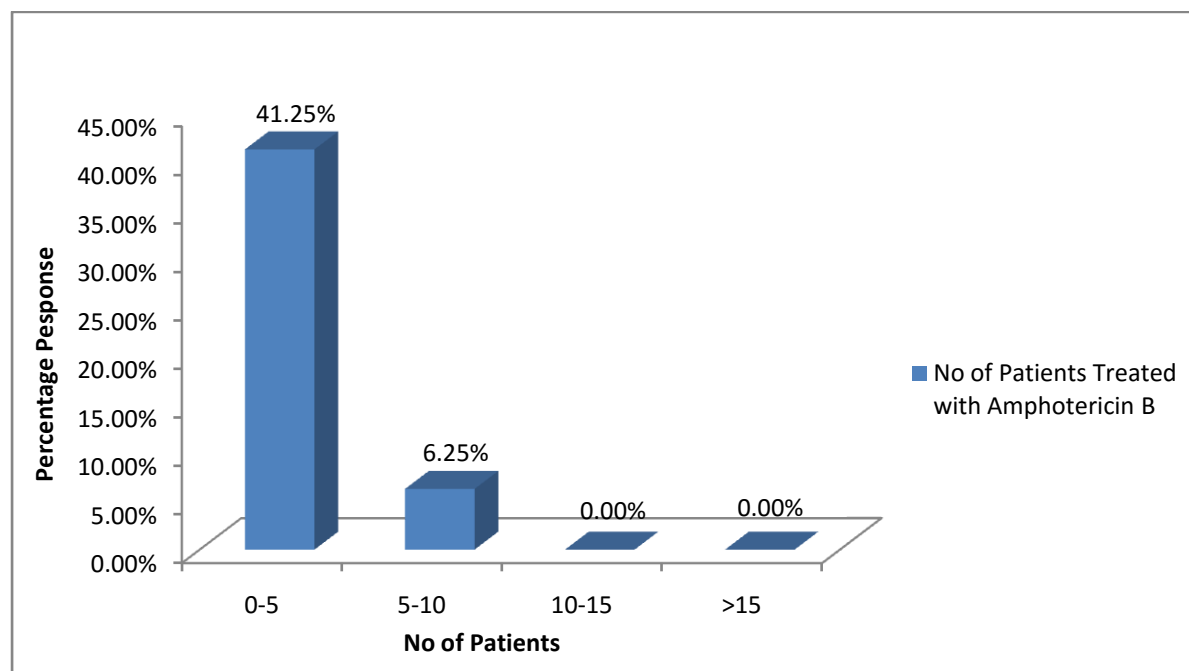


Figure 10: Total Number of Patients Treated with Amphotericin B vs Percentage Response (Per Month)

Government vs Private Hospitals

While comparing government and private hospitals it was found that 25% government and 16% private specialists prescribed Amphotericin B to 0-5 patients. Followed by 5% government and 1.25% private specialists prescribing to 5-10 patients.

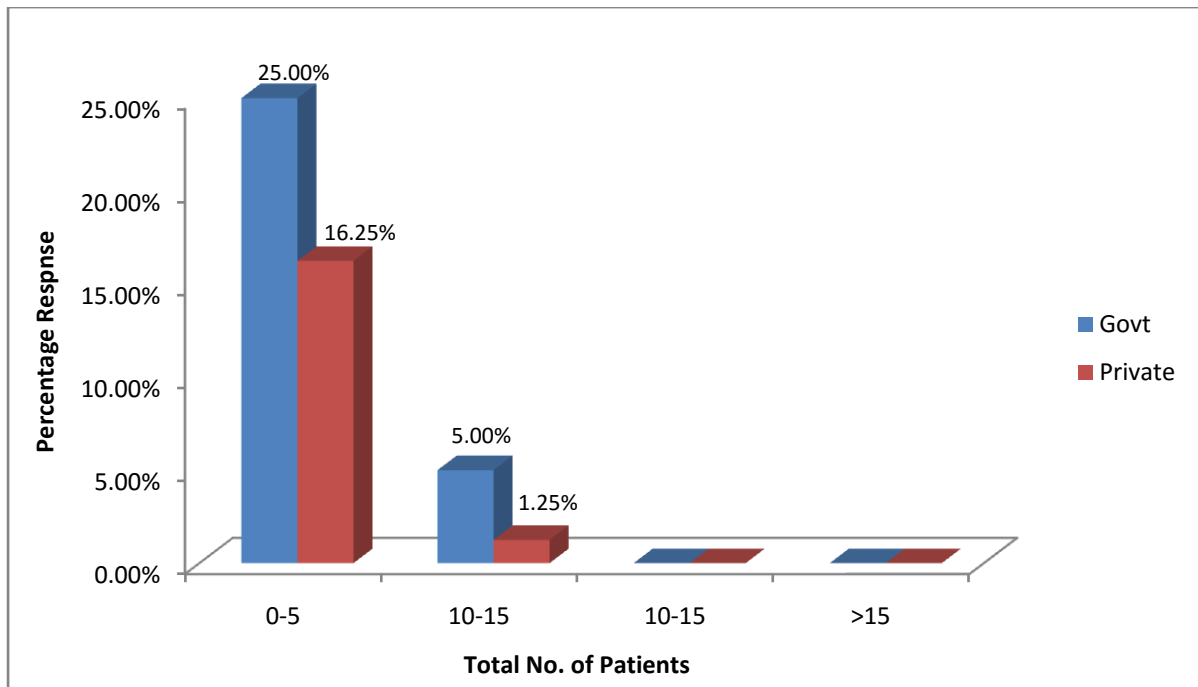


Figure 11: Total Number of Patients Treated with Amphotericin B in Government and Private Hospitals vs Percentage Response (Per Month)

Objective 4: To study the duration of treatment in terms of vials used

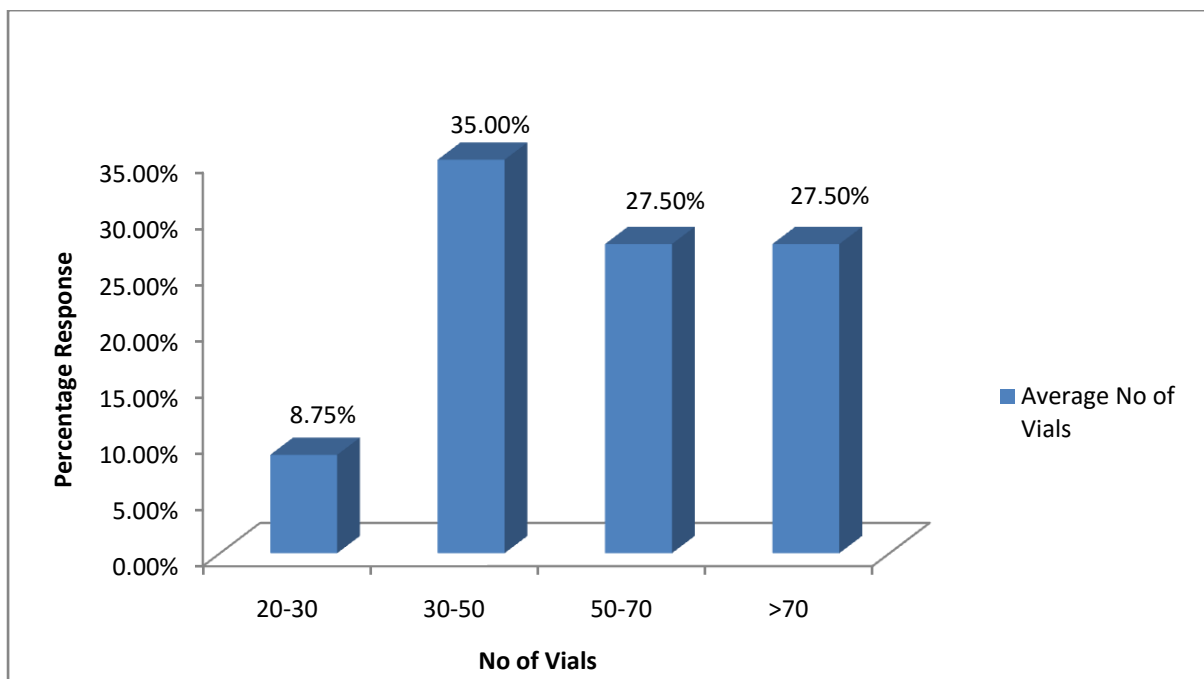


Figure 12: Average Number of Vials vs Percentage Response

When asked about the average number of vials used for the complete treatment of mucormycosis with each vial having 50mg dose 35% responses were about using 30-50 vials. Followed by 27.50% responses for 50-70 vials and similar results were also obtained for more 70 vials.

Approximately 9% responded about using 20-30 vials for the treatment.

Government vs Private Hospitals

While comparing government and private specialists it was found that 7.50% government and 10% private hospital specialists responded about using 20-30 vials.

Average of 30-50 vials were used by 27.50% government and 42.50% of private hospital specialists for the treatment of mucormycosis.

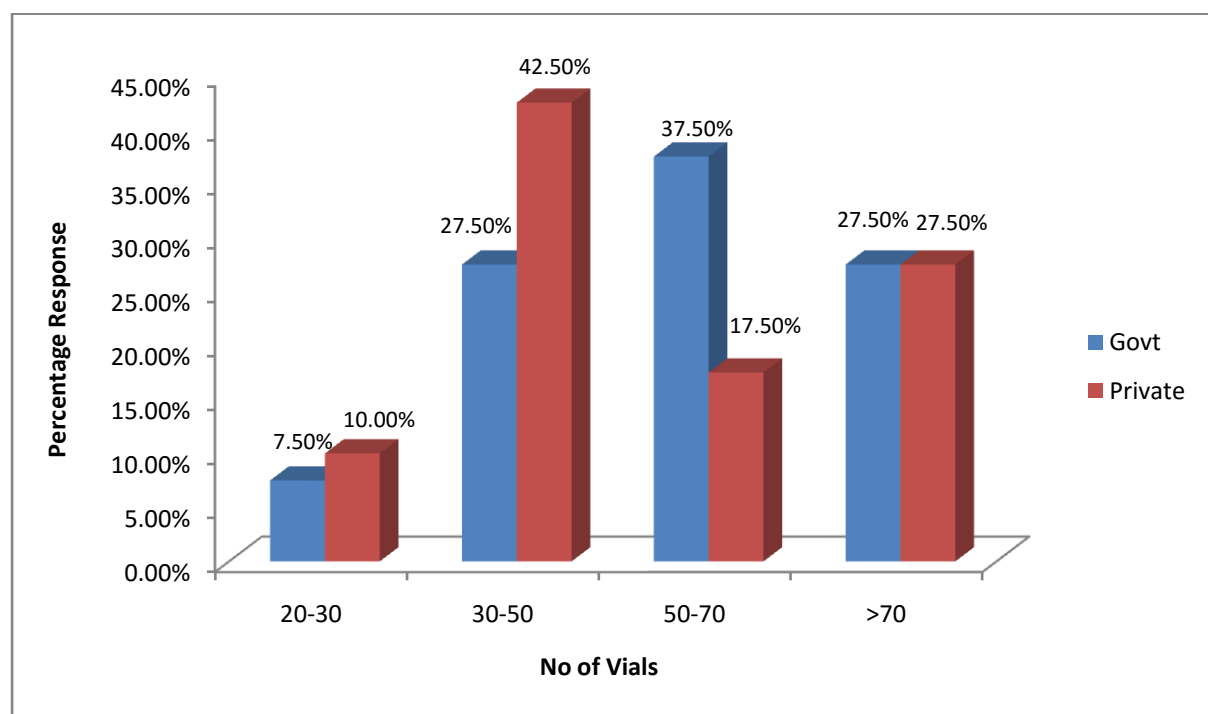


Figure 13: Average Number of Vials (Govt. & Private Hospitals) vs Percentage Response

37.50% responses from government and 17.50% responses from private specialists were received for the use of an average of 50-70 vials.

27.50% responses were for the use of more than 70 vials of both government and private hospital specialists.

Other Findings

Various other findings of the project are:

1. Almost all patients require surgical debridement of infected tissue.
2. Mostly occurs in immunocompromised patient.
3. Underlying cause such as Diabetes needs to be controlled for the treatment to be effective.
4. Minimum of 4-6 weeks treatment is mandatory.
5. Posaconazole can also be given along with Liposomal Amphotericin B for better effect.
6. Diagnostic Tests are required for starting the treatment to completely identify the nature of infection.

Limitations to the study

- Doctors were not ready to give information easily.
- Question regarding the brand of preference was not answered by the majority of doctors.
- Stages of disease could have been specified.

Recommendations

This study gives quite a clear picture about mucormycosis and various treatment measures. This study reveals that-

- ✓ Mucormycosis as a rare infection, not much of the patients are detected with this.
- ✓ Liposomal Amphotericin B is most prescribed drug followed by Amphotericin B.
- ✓ Most patients are detected in the advanced stage of infection which requires longer treatment. This shows that even though mucormycosis is a rare infection but there is a big market for mucormycosis. On average each patient requires 50-70 vials for treatment.

Way Ahead

- Liposomal Amphotericin B is most prescribed drug and BSV is already manufacturing it. But as India is low-middle income group and most of the people who get affected by this infection are from low-income group. So most of them cannot afford to this expensive treatment of mucormycosis. There is dire need to generate affordable treatment measures for this. If an affordable formulation better than Liposomal Amphotericin B and low cost is discovered, it can easily gain a status of market leader.
- R&D is another area where BSV can venture into for the improvement of the existing formulation of Amphotericin B.
- Posaconazole is most prescribed azole for mucormycosis. It is also used in combination with Liposomal Amphotericin B by few of specialists. This is the area where BSV can venture into.
- It is difficult to identify mucormycosis in the initial stages so there is a need for a technique for easy detection of infection in the initial stage.

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Annexure

Questionnaire

Name of Doctor: _____

Date of Visit: _____

Speciality: _____

Hospital Attached: _____

Contact No: _____

Name of student: _____

Q-1 – How many of Number Mucormycosis patients detected in your practice / month?

☐ 0-5 ☐ 5-10 ☐ 10-15 ☐ > 15

Q-2 – At what Stage Mucormycosis disease is detected?

Q-3 - How do you manage these patients?

☐ Refer to other Drs /Hospital ☐ treat in your hospital

Q-4 – If you refer – can you please share name of Dr/Hospital?

Q-5- What is your line of treatment?

☐ Azole s ☐ Amphotericin ☐ Liposomal Amphotericin B

Q-6 – What is your preference?

1) Azole - Preferred Drugs a) _____ b) _____ c) _____

2) Liposomal Amphotericin B brands – a) _____

b) _____

c) _____

Q-7- How many patients are treated with Amphotericin B?

☐ 0-5 ☐ 5-10 ☐ 10-15 ☐ > 15

Q-8 - How many patients are treated with Liposomal Amphotericin B?

☐ 0-5 ☐ 5-10 ☐ 10-15 ☐ > 15

Q-9: What is the Duration of Treatment in terms of Dose Rx (No. of Vials?)

☐ 20- 30 ☐ 30- 50 ☐ 50- 70 ☐ >70

Q-10 would like to share any other critical Information Related to Mucormycosis?
