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# A Comparative Study of 7 Days Versus 14 Days of Empirical Antibiotic Therapy in The Treatment of Uncomplicated Bacterial Meningitis Cases Up to Two Months Of Age

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## ABSTRACT
**Background:** In newborns, acute bacterial meningitis (ABM) is a serious illness of the central nervous system that frequently results in hospitalization. Shorter duration antibiotic treatment has recently been demonstrated as effective as longer ones. This strategy will reduce the length of hospital stay and medicine expenditures as well. **Objectives:** To evaluate the differences between 7-day and 14-day antibiotic therapy for uncomplicated bacterial meningitis in patients up to two months old in terms of clinical effectiveness (improvement of signs and symptoms) and outcomes (duration of hospital stay, patient compliance, treatment costs, sequelae). **Methods:** 84 patients of both sexes with uncomplicated meningitis in the infant ward of the neonatal incentive care unit (NICU) at Dhaka Shishu (Children) Hospital (DSH), ages from 0 to 2 months, participated in this randomized clinical research. Clinical severity, length of hospital stays, patient compliance, treatment expenses, and complications were documented following 7 and 14 days of antibiotic therapy for groups, A (40 patients) and B (44 patients). Multiple linear regression analysis, Spearman correlations, and group comparisons were conducted. **Results:** Mean time to resolve fever was 2.65±0.74 days for group A and 2.71±0.69 days for group B; mean time to halt convulsions was 2.46±0.39 days for group A and 2.38±0.43 days for group B. Group A's mean hospital stay was 8.48±0.17 days, whereas Group B was 16.82±6.12 days. Sepsis was significantly marked in group B (11.4%). **Conclusion:** For uncomplicated bacterial meningitis up to two months of age, shorter duration antibiotic treatments are more beneficial in reducing hospital-associated sepsis, morbidity, and expenses.



## INTRODUCTION:
Bacterial meningitis, a significant global public health issue, is an infection of the central nervous system that results in considerable morbidity and mortality in infants, particularly in developing countries [1]. Approximately 1-2 million cases of bacterial meningitis are diagnosed worldwide each year [2]. Acute bacterial meningitis of the lepto-meninges is typically caused by bacteria present in the subarachnoid space [1]. Meningitis can occur in all age

groups, with the peak incidence occurring during the first two years of life. The classic triad of meningitis includes fever, headache, and neck stiffness. In young infants, these features may be subtle, variable, non-specific, or even absent. Infants are often observed with fever, lethargy, irritability, poor feeding, vomiting, convulsions, and bulging fontanelles. The causes of meningitis can be infectious (bacterial, viral, fungal) or non-infectious [1]. In young infants, the most common causes of bacterial meningitis are Escherichia coli, Klebsiella, group B Streptococcus, Listeria monocytogenes, and Streptococcus pneumoniae [3]. While Group B Streptococcus (GBS) has been the most common organism in developed countries, in Bangladesh, E. coli, Klebsiella, and Pseudomonas are the major causative organisms for the development of meningitis [4].

Early identification and prompt antibiotic treatment are crucial for reducing mortality and morbidity. Antibiotic therapy administered to young infants with bacterial meningitis leads to rapid sterilization of cerebrospinal fluid in nearly all patients. Bacterias are eradicated from the CSF within 24 to 48 hours of starting parenteral therapy [3]. Consequently, post-infection complications arise not from ongoing bacterial replication but rather from ischemic damage and inflammation triggered by the initial bacterial infection [5].

In cases of bacterial meningitis, antibiotic treatment is prolonged and maintained in infants and children with neurological complications, even when viable bacteria are absent, due to the physician's concern about premature cessation[6]. Overutilization of antibiotics in hospitalized patients is a major risk factor for the development of antibiotic resistance. A study from Bangladesh indicated that, the most common causes of meningitis were Klebsiella, Staphylococcus aureus, and E. coli, which exhibited 100% resistance to ampicillin and very poor sensitivity to gentamicin. Gram-negative isolates showed high sensitivity to amikacin and imipenem, while gram-positive isolates were highly sensitive to amikacin and vancomycin [4].

In 2010, a study result show that a shorter duration of therapy is proven to be equally effective; it will not only reduce the cost of the drug but also decrease the number of days of hospitalization. This approach will benefit developing countries with limited resources and will also ensure better patient compliance [7]. Some studies state that 7 days course of antibiotic therapy is effective for young infant in bacterial meningitis. Here is a notable difference between reports from developed and developing countries regarding the fatality rate and frequency of complications of ABM. This primarily reflects the issues with treatment among children and infants in developing countries, which are attributed to delayed admissions and poor nutritional status. Additionally, there is a low yield of causative organisms, mainly due to the use of pre-hospital antibiotics [8]. In Bangladesh, there is high burden of meningitis in infants. There are limited studies to evaluate the effect of short duration of antibiotic therapy in meningitis of young infant in Bangladesh. So, there is a need for surveillance of duration treatment in cases of uncomplicated bacterial meningitis up to two months of age. This study helps us to compare short duration (7 days) versus long duration (14 days) treatment and outcome of bacterial meningitis up to two months of age.

## MATERIALS AND METHODS:

This randomized clinical trial was conducted in in the infant ward of the neonatal incentive care unit (NICU) at Dhaka Shishu (Children) Hospital, during the period from august 2018 to august 2020. A total 84 eligible neonates with meningitis, ages from 0 to 2 months with history of fever, alteration of activities, poor feeding, convulsion, vomiting, bulging anterior fontanelle and positive CSF analysis for cytology, biochemistry, gram staining and/ or culture and sensitivity were enrolled. Patient with meningitis secondary to ventriculo-peritoneal shunt, history of any neurosurgery within a month of meningitis diagnosis, immunosuppression, major congenital anomaly, seizure disorder, sequels of perinatal asphyxia, meningitis other than bacterial cause were excluded. The diagnosis of neonatal meningitis was made on the basis of presence of WBC count>20,000/cumm or WBC count <5000/cumm; raised immature/total neutrophil ratio (>0.2), CRP >10 mg/l on blood sample and in case of CSF study-≥ 30 cells ⁄mm3, protein>150 mg/dl, sugar <30 mg/dl, (Mathur *et al*.2015)

After proper approval from the ethical review committee (ERC) of DSH, patients of meningitis were included in the study after taking proper informed written consent from the parents or local guardians. The purpose, procedure, importance and benefit of the study were explained to the parents. A detailed history of age, sex, vaccination, duration of fever, convulsion, irritability, vomiting, feeding intolerance, and impaired level of consciousness was taken from each patient through questionnaire. Physical examinations were done to find out the pulse rate and volume, respiratory rate, blood pressure, consciousness level, modified GCS score, bulged fontanelle, focal neurological sign. Then blood was collected for Complete Blood Count, CRP and blood Culture and Sensitivity. Lumber puncture was done for CSF analysis for cytology, biochemistry, staining, Culture and Sensitivity, Latex Agglutination Test and PCR. The specimens were tested at the Dhaka Shishu Hospital microbiology laboratory. All patients got meropenam (120mg/kg/day-in 3 divided doses) and vancomycin (45 mg/kg/day in 3 divided doses) as per

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unit protocol. Dexamethasone in the dose of 0.15mg/kg was given intravenously every 6 hour for 48 hours. Other supportive care (antipyretics, I/V fluids, oxygen inhalation, oropharyngeal suction) was given equally to all the patients as protocol of treatment. After 7 days of treatment again Lumber puncture was done in all patients for CSF analysis for cytology, biochemistry, staining, culture and sensitivity, Latex Agglutination Test and PCR also USG of brain was done in all patients and if needed CT scan was also done. The patients who had clinical remission, normal CSF and no evidence of infection on cranial ultrasonography were enrolled in the study (on day 7 of antibiotic therapy). After exclusion of all treatment failure who scored 10 (Singhi *et al*.2002) or more randomization of young infants to Group A (7 days antibiotic therapy) or Group B (14 days of antibiotic therapy) was done by lottery method on the seventh day. Patients in the group A were monitored for next 2 days. Danger signs (poor feeding, lethargy, cough, chest retractions, diarrhea, seizures and abdominal distension) were explained at the time of discharge with the advice to report immediately in case of any symptoms. To see outcome (disease complication such as hydrocephalus, seizure disorder, developmental delay, hemiplegia, hearing loss, cognitive difficulties) we gave follow up the patient at the 1 month after discharge and also follow up after 3 months from first follow up. Mortality cases were also enrolled.

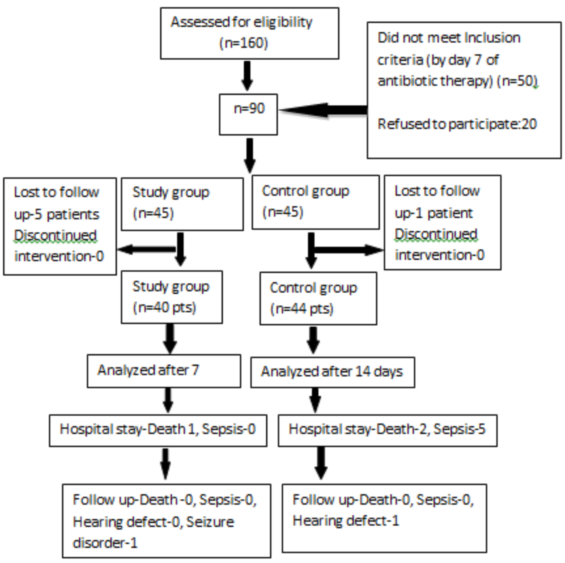

**Fig 1: Flow chart of study**

## RESULTS:

This study included 84 pediatric patients (Group A: n=40; Group B: n=44) with comparable age (1.30±0.46 vs 0.98±0.45 months, p=0.082) and sex distribution (M/F: 65/35% vs 45.5/54.5%, p=0.072). All patients presented with fever and convulsions; vomiting (92.5% vs 79.5%), feeding intolerance (82.5% vs 90.9%), lethargy (97.4% vs 90.9%), and hypoxia (43.6% vs 22.7%) were common. Blood cultures most frequently yielded Klebsiella (2.5% vs 11.4%), with Acinetobacter significantly higher in Group B (0% vs 9.1%, p=0.040). CSF cell counts and protein decreased from day 1 to day 7 (Cell count: 216.9±219.5 to 11.9±8.6 vs 308.8±247.4 to 11.6±8.2). Mean hospital stay was longer in Group B (16.82±6.12 vs 8.48±0.17 days, p<0.001), and sepsis was more frequent (11.4% vs 0%, p=0.021). Follow-up adverse outcomes were rare, with isolated seizure disorder (2.5%) and hearing abnormality (2.4%).

**Table 1: Baseline characteristics of study population**

| Variables | Group A ( n=40) | Group B (n=44) | p-value |
|---|---|---|---|
| **Age (months) mean (SD)** | 1.30 (0.46) | 0.98 (0.45) | 0.082 |
| **Sex M/F n (%)** | 26/14 (65/35) | 20/24 (45.5/54.5) | 0.072 |
| **Clinical features at presentation** | | | |
| **Fever n (%)** | 40(100.0%) | 44(100.0%) | 1.000 |
| **Convulsion n (%)** | 40(100.0%) | 44(100.0%) | 1.000 |
| **Unconsciousness n (%)** | 3(7.5%) | 0(0.0%) | 0.064 |
| **Vomiting n (%)** | 37(92.5%) | 35(79.5%) | 0.090 |
| **Feeding intolerance n (%)** | 33(82.5%) | 40(90.9%) | 0.354 |
| **Lethargy n (%)** | 37(97.4%) | 40(90.9%) | 0.223 |
| **Hypoxia n (%)** | 17(43.6%) | 10(22.7%) | 0.073 |
| **Hypoglycemia n (%)** | 5(12.5%) | 3(6.8%) | 0.327 |
| **Hypothermia n (%)** | 2(5.0%) | 5(11.4%) | 0.235 |
| **Shock n (%)** | 1(2.5%) | 1(2.7%) | 1.000 |

**Chi-squared Test ($\chi^2$) was done to analyze the data, *significant (p<0.05)**

Table I shows, non-significant age and sex distribution between groups. All patients had fever and convulsion. Vomiting, feeding intolerance, irritation. hypoxia were also common symptoms in between two group. Unconsciousness was found 3 patients in group A. Shock was found in 2 patients from both groups. The data were not statistically significant (p<0.05) between two groups.

**Table 2: Organisms isolated in blood/CSF cultures in the study population (n=84)**

| Blood culture | Group A (n=40) No. (%) | Group B (n=44) No. (%) | p-value |
|---|---|---|---|
| **Klebsiella** | 1(2.5%) | 5(11.4%) | 0.089 |
| **Staphylococcus aureus** | 1(2.5%) | 0(0.0%) | 0.314 |
| **Coagulase-negative Staphylococcus** | 0(0.0%) | 0(0.0%) | |
| **Pseudomonas** | 0(0.0%) | 2(4.6%) | 0.152 |
| **Acinetobacter** | **0(0.0%)** | **4(9.1%)** | **0.040*** |
| **Streptococcus pneumonia** | 0(0.0%) | 0(0.0%) | - |
| **CSF culture** | | | |
| **E. coli** | 1(2.5%) | 3(6.8%) | 0.304 |

**Chi-squared Test ($\chi^2$) was done to analyze the data, *significant (p<0.05)**

Table 2 shows the bacteriological etiology of detect bacterial etiology from CSF and blood culture. Most common organism is Klebsiella in both group, Significant difference was found between two groups in case of Acinetobacter; was found only in group B.

**Table 3: Comparison of CSF parameters in study population (n=84)**

| CSF parameters | Group A (n=40) | Group B (n=44) | p-value |
|---|---|---|---|
| **Cell count day1 mean ± SD** | 216.9±219.5 | 308.8±247.4 | 0.083 |
| **Cell count day 7 mean ± SD** | 11.9±8.6 | 11.6±8.2 | 0.385 |
| **Protein day 1 mean ± SD** | 226.3±145.5 | 209.9±89.1 | 0.545 |
| **Protein day 7 mean ± SD** | 95.1±58.1 | 114.3±161.2 | 0.482 |
| **Sugar day1 mean ± SD** | 33.1±9.1 | 28.9±12.4 | 0.088 |
| **Sugar day 7 mean ± SD** | 34.5±6.7 | 30.9±11.0 | 0.079 |
| **Positive CSF culture n (%)** | 1(2.5%) | 3(6.8%) | 0.356 |
| **Negative CSF culture n (%)** | 39(97.5%) | 41(91.3%) | 1 |
| **Positive gram stain n (%)** | 2(5.0%) | 5(11.4%) | 0.235 |
| **Negative gram stain n (%)** | 38(95.0%) | 39(88%) | |

**Chi-squared Test ($\chi^2$) was done to analyze the data, *significant ($p<0.05$)**

Table 3 shows that CSF cell & protein count reduced from D1 to D7, after 7 days antibiotics and dexamethasone.

**Table 4: Comparison of clinical efficacy & adverse outcome during hospital stay of the study subjects (n=84)**

| Clinical efficacy | Group A (n=40) Mean±SD | Group B (n=44) Mean±SD | p-value |
|---|---|---|---|
| **Mean time to resolve fever (days)** | 2.65±0.74 | 2.71±0.69 | 0.702 |
| **Mean time to improved tachypnea (days)** | 2.21±0.47 | 2.39±0.42 | 0.078 |
| **Mean time to stop convulsion (days)** | 2.46±0.39 | 2.38±0.43 | 0.376 |
| **Mean time for oxygen therapy (days)** | 1.87±0.21 | 1.78±0.25 | 0.239 |
| **Mean length of hospital stays (days)** | 8.48±0.17 | 16.82±6.12 | **<0.001*** |
| **Adverse outcome** | N (%) | N (%) | p-value |
| **Sepsis** | 0(0.0%) | 5(11.4%) | **0.021*** |
| **Death** | 1(2.5%) | 2(4.6%) | **0.556** |
| **Hydrocephalus** | 0(0.0%) | 1(2.4%) | **0.314** |
| **Abnormal cranial USG/ convulsion** | 0(0.0%) | 0(0.0%) | - |

**Chi-squared Test ($\chi^2$) was done to analyze the data, *significant ($p<0.05$)**

Table 4 shows mean length of hospital stay between two groups was statistically significant ($p<0.05$) During hospital stay, sepsis was significantly more common in group B.

1 patient died in group A and 2 patients died in group B as well.

**Table-5: Adverse outcome during follow up (n=84)**

| Adverse outcome | Group A (n=40) No. (%) | Group B (n=44) No. (%) | p-value |
|---|---|---|---|
| **Death** | 0(0.0%) | 0(0.0%) | - |
| **Hydrocephalus** | 0(0.0%) | 0(0.0%) | - |
| **Hearing abnormality** | 0(0.0%) | 1(2.4%) | 0.314 |
| **Developmental delay** | 0(0.0%) | 0(0.0%) | - |
| **Coagulation impairment** | 0(0.0%) | 0(0.0%) | |
| **Seizure disorder** | 1(2.5%) | 0(0.0%) | 0.314 |

**Chi-squared Test ($\chi^2$) was done to analyze the data, *significant ($p<0.05$)**

Table 5 shows; seizure disorder was found in 1 patient in group A and 1 patient was suffering from hearing abnormality in group B.

## DISCUSSION:

This study was carried out in neonatal unit, NICU and infants less than two months of age in different units of Dhaka Shishu (Children) Hospital, from July 2018 to July 2020. In this study 84 patients of 0-2 months of age with acute meningitis were included.

In this study, no significant ($p>0.05$) age and sex difference were found between two groups; though majority of patients were male, below 1 month of age. Similar findings were found by Mathur et al. (2015) & Singhi et al. (2002). One of the reasons of more meningitis in neonate is due to maternal infection that may be transmitted to neonate in utero or during birth [8,9]. Another reason is neonate's ability to resist infection is limited by its immature immune system [10]. Again, the high incidence of acute meningitis in males as compared to females may be attributed to presence of two X chromosomes which provide greater genetic diversity to the female immunologic defenses (George and Jorge 1997). It could also be due to greater health care seeking attitude of parents towards the male child in the Indian Subcontinent [11].

Current study shows that, common presenting symptoms of meningitis among neonates were found as fever, convulsion, vomiting and feeding intolerance which is in line with Singhi et al. (2002) [8]. But they found poor feeding in very few patients which differs from our study possibly due to enrollment of meningitis patient below two months of age in this study.

In this study significant amount of *Acinetobacter* were

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found in group B. among 14 culture positive patients; 11 were from group B. Similar findings were found by Mathur et al. (2015); Singhi et al. (2002) [8,12]. Group B was much affected with organism due to prolong hospital stay. Excessive over-utilization of antibiotics in hospitalized patients is one of the major risk factors for development of antibiotic resistance. This could be a probable factor explaining higher rates of recurrence of sepsis and mortality in the control group.

In this current study within 7 days of antibiotic therapy, cell count and protein were reduced and culture became negative. These results were in line with Singhi et al. (2002); Mathur et al. (2015). Antibiotic causes rapid sterilization of CSF fluid as well as elimination of bacterias within 48 to 72 hours of therapy. Anti-inflammatory therapy by dexamethasone in bacterial meningitis has been shown to decrease meningeal inflammation, blood–brain barrier permeability, intracranial hypertension, brain edema, tissue damage, long-term neurological sequelae and mortality rates associated with this disease [8,12].

In present study, no statistically significant difference was found in terms of tachypnea improvement, subsidence of fever, duration of oxygen therapy, stopping convulsion between two groups, that means improvement of symptoms are not associated with duration of treatment. Early diagnosis and prompt antibiotic therapy can prevent brain damage and thereby improvement of symptoms. These findings were similar to studies done by Mathur et al., (2015); Singhi et al., (2002); Kavaliotis et al., (1989) and Koedel et al., (1995) [8,12,13,14]. In this study, hospital stay and mortality were more in case of group B. Due to prolong hospital stay group B patients were more vulnerable for nosocomial infection, antibiotic resistance and sepsis.

We also found that rate of complications and sequelae and occurrence of seizures in babies who received antibiotics for 7 days was similar to those who received 14 days of antibiotic therapy. Lin et al. (2012) also found that duration of therapy did not alter frequency of seizures in children with meningitis. Jadavji et al. (2014) found that frequency of observed sequelae of short duration therapy was similar to that previously reported in children for 10-14 days [5,15]. The fact that there was no difference in the complications and sequelae in two groups supports the view that prolonged antibiotic therapy does not reduce complications or sequelae. As these are the result of ischemic and inflammatory damage initiated by original bacterial infection and not because of continued bacterial replication [5,15]. Reduced mortality and morbidity are likely to result from early diagnosis and treatment. In this current study we found that shorter course of antibiotic therapy can potentially decrease the duration of hospitalization, drug resistance and number of adverse events thus reduce the healthcare costs also could conserve the limited resources available in low-income countries. Prolonged exposure to antibiotics tends to increase probability of emergence of resistant strains of bacteria. Follow up of 90 days was considered sufficient. However, a longer follow-up is desirable.

This study has also some limitations. Too little sample size and this study was conducted in Dhaka city, which didn't reflect the entire picture of whole country. Again, frequent follow up was recommended.

## CONCLUSION:

Shorter duration of antibiotic therapy is more effective and has a positive impact towards hospital associated sepsis, morbidity and costs in comparison to longer duration of antibiotic in case of uncomplicated bacterial meningitis up to two months of age.

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