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CLINICAL AUDIT ON COMPLIANCES WITH THE STANDARD TREATMENT GUIDELINES AMONG PATIENTS DIAGNOSED WITH DENGUE FEVER IN A TERTIARY CARE TEACHING HOSPITAL, KARNATAKA, SOUTH INDIA – A QUALITY IMPROVEMENT PROJECT.

General Medicine

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ABSTRACT

BACKGROUND: - Evaluation and improvement of quality of care provided to the patients are of crucial importance in the daily clinical practice and in the health policy planning and financing. Different tools have been developed, including incident analysis, health technology assessment and clinical audit. Audits and quality improvement projects are vital aspects of clinical governance and continual service improvements in medicine. Dengue is a vector borne viral disease which occurs in tropical and sub - tropical regions around the world. Clinical audit aims to identify the gaps between established norms and practiced norms. Herein, we present 51 cases from more recent clinical experience that demonstrate the adherence of Platelet transfusion and Fluid replacement therapy against dengue virus infection to the set standards.

AIM & OBJECTIVES:- To improve the care of patients presenting with dengue fever at various stages and to Evaluate the Adherences to Standard Treatment Guidelines among Patients Diagnosed with Dengue fever.

METHODS:- Retrospective observational study was undertaken among adult patients in a tertiary care teaching hospital. Fifty one patient's case records were studied and analysed. All patients who were NS1 antigen / IgM dengue positive were included in the study. Clinical features, hematological and biochemical parameters were noted. Paediatric patients were excluded from the study.

RESULTS:- Out of 51 patients 29 were NS1Ag positive. 24 patients were in dengue fever without any critical signs. 9 each were in DHFI and DHFII. 4 were in DHF III. 5 were in DHFIV. 4 out 9 DHFI grade did not received adequate fluids and 3 out of 9 in DHF II did not received adequate fluids. All DHFIII, DHFIV patients were managed as per guidelines. Platelets transfusion done for all 5 patient with stage DHFIV

CONCLUSION: - Clinical audit is a quality improvement process that measures current patient care and outcomes against agreed standards of best practice. Diagnosis of the illness and grading the severity of the illness is as per Indian national guidelines for dengue. So effectively 7 out of 51(13.68%) patients did not receive fluids therapy as per Indian National Dengue Guidelines. Audits and quality improvement projects are vital aspects of clinical governance and continual service improvement in medicine.

KEYWORDS

Dengue fever, clinical Audit, Platelet transfusions, Fluids, Quality.

INTRODUCTION:-

Evaluation and improvement of quality of care provided to the patients are of crucial importance in the daily clinical practice and in the health policy planning and financing. Different tools have been developed, including incident analysis, health technology assessment and clinical audit. The clinical audit consist of measuring a clinical outcome or a process, against well-defined standards set on the principles of evidence based medicine in order to identify the changes needed to improve the quality of care. Medical audit is defined as the evaluation of medical care in retrospect. Clinical (or medical) audits are part of the continuous quality improvement process that focus on specific issues or aspects of health care and clinical practice.[1] Dengue is a vector borne viral disease which occurs in tropical and sub - tropical regions around the world. Aedes aegypti is the main vector of Dengue transmission in India. Another important vector is the Aedes albopictus. The infection is transmitted by the bite of an infected female mosquito Aedes aegypti. The incubation period of Dengue fever is usually 5 - 6 days, but may vary from 3 to 10 days. Dengue fever is the most rapidly spreading vector borne viral disease and is a major international public health concern. World Health Organization (WHO) currently estimates there may be 50 million cases of Dengue infection worldwide every year. It often manifests with fever, joint pain, and rash, but to date there is no specific drug available to treat it.[2] Infection with the dengue virus can result in a variety of clinical states ranging from 'asymptomatic' to mildly symptomatic Dengue Fever (DF) to more dangerous clinical conditions with capillary leakage syndrome such as Dengue Hemorrhagic Fever (DHF), resulting in bleeding, low levels of blood platelets and blood plasma leakage or into Dengue Shock Syndrome (DSS) where dangerously low blood pressure occurs.[3] The basics of management of cases of Dengue fever are fluids, rest, antipyretics. In Dengue Shock Syndrome volume replacement is the most important treatment measure and immediate administration of intravenous fluids to expand plasma volume is essential. Clinical audit is a critical analysis of the quality of medical care given to the patient starting from diagnosis to the final discharge process, the use of various organizational resources of manpower, equipment medicines etc., the outcomes of medical interventions done at hospital level and the quality of life of the patient receiving care. The clinical audit consist of measuring a clinical outcome or a process, against well-defined standards set on the principles of evidence-based medicine in order to identify the changes needed to improve the quality of care i.e., aims to identify the gaps between established norms and practiced norms.[4] In particular, patients suffering from dengue viral infection, present with many problems like hypovolemia and thrombocytopenia and so adequate and appropriate management is required that have been set as topics for clinical audit projects. This lets care providers and patients know where their service is doing well, and where there could be improvements. Clinical audit comes under clinical governance umbrella and forms part of the system for improving the standard of clinical practice.[5]

The purpose of this audit was to improve the quality of care to patients presenting at various stages of Dengue Fever at our medical college, hospital and is aimed to highlight the deficiencies between actual practice and set standards (National dengue Clinical Practice Guidelines, for the initial clinical assessment, diagnosis and management practices) through the systematic assessment in order to improve the quality of care.

Audits are quality improvement measures and one of the 7 pillars of clinical governance. It allows organizations to continually work toward improving quality of care by showing them where they are

falling short, allows them to implement improvements, and reaudit or close the audit cycle to see if beneficial change has taken place.[6]

AIM:- Aim of this audit is to highlight the discrepancies between actual practice and standard in order identify the changes to improve the quality of care of patients presenting with dengue fever at various stages.

OBJECTIVES:-
• To evaluate the adherence of fluid management guidelines in Dengue hemorrhagic fever grade I, II, III, IV patients admitted to our hospital as per Indian National Dengue Guidelines.
• To evaluate the adherence of Platelet transfusion guidelines in Dengue patients admitted to our hospital as per Indian National Dengue Guidelines.

MATERIALS & METHODS:-
The audit was conducted in the following steps

Step 1:- Preparing for the audit
Dengue fever has been selected as a topic for this clinical audit and objectives were clearly defined.

Step 2:- Selection of indicators, criteria and standards and definition of intervention strategies:-
Indian national guidelines for dengue fever treatment has been selected as standards to evaluate the adherence of fluid replacement therapy and platelet transfusions.

Step 3:- Data collection
Data was collected retrospectively by utilizing the patient's case records. Patients who were admitted for treatment of dengue fever from May 2018 to July 2018 were considered. A data collection form was designed to obtain the audit data.

Inclusion Criteria: - All patients above with confirmed dengue, who were hospitalized with NS1 (nonstructural protein) antigen and / or IgM dengue antibody positivity were included in the study

Exclusion Criteria: The Patients with Cardiovascular disease with LV dysfunction, AKI, Chronic kidney disease etc. were excluded from the study. Peadiatric age groups were also excluded.

Convenience sampling was used for this clinical audit project. A total of 52 patients were selected. The age, sex, clinical stage at which patient has been presented , the amount of fluid at which patient resuscitated, the lowest platelet count at which patient has been transfused platelets were assessed. The data was analysed using Microsoft excel in the form of descriptive statistics and results were interpreted and concluded.

Step 4:- Comparison of collected data with the standards and development of corrective actions
This is the central phase of clinical audit. In this step, the data collected through audit was analysed and compared them with the pre-set standards.

Step 5:- Check and maintenance of improvements
It is essential for a proper process of clinical audit to schedule periodic verifications of the effects of the changes introduced.

OBSERVATIONS & RESULTS:-
A total of 51 patients' case records were audited, out of which 35 were males and 16 were females. About 9 patients had platelet count ranging between 50,000 to 0ne lakh and 7 patients had platelet count ranging between 10,000 to 50,000 mm³.

Table no.1:- Gender wise Distribution of patients

Gender of patients	No. of patients n =51
Males	35
females	16

Table no.2:- Age wise Distribution of patients

Age range of patients	No. of patients n =51
Less than 30yrs	5
31 – 40yrs	14
41 – 50yrs	16
51 – 60yrs	10
More than 60yrs	6

Table no.3:- Positivity with Dengue serology

Positivity of dengue serology	No. of patients (N = 51)
NS1 Antigen	29
IgM Antibody	8
Both NS1 Antigen and IgM Antibody	14

Table no.4:- Grading of Dengue fever according to stages

Grading of Dengue fever	No. of patients N=51
Dengue Fever	24
Dengue Haemorrhagic Fever I	9
Dengue Haemorrhagic Fever II	9
Dengue Haemorrhagic Fever III	4
Dengue Haemorrhagic Fever IV	5

Table no.5:- Adequacy of Fluid Replacement therapy

Adequacy of Fluid Replacement therapy		
Dengue fever grade	Patients who received Adequate fluids	No.of patients whose fluid replacement was inadequate
Dengue Fever	24	0
Dengue Haemorrhagic Fever I	5	4
Dengue Haemorrhagic Fever II	6	3
Dengue Haemorrhagic Fever III	4	0
Dengue Haemorrhagic Fever IV	5	0

Table no.6:- Platelet transfusion Therapy

Platelet Transfusion therapy		
Platelet counts range of patients	No. of patients N =51	No. of patients who received Platelet transfusions
More than one lakh	31	0
50,000 – one lakh	9	1 out of 9 patients
10,000 – 50,000	7	2 out of 7 patients
Less than 10,000	4	4

DISCUSSION:-
Clinical audit is a part of the continuous quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change[4]

The diagnosis of dengue fever may be confirmed by microbiological laboratory testing. National Vector Borne Disease Control Program (NVBDCP), Govt. of India recommends use of enzyme linked immunosorbent assay (ELISA)-based antigen detection test (NS1) for diagnosing the cases from day one onwards and antibody detection test immunoglobulin M (IgM) capture ELISA (MAC-ELISA) for diagnosing the cases after 5th day of onset of disease to confirm dengue infection.[7] The viral protein NS1 is an ideal diagnostic target because it is secreted from infected cells and is found at high levels circulating in the blood of infected individuals,[8] and detection of NS1 during febrile phase of a primary infection may be greater than 90% sensitive however only 60-80% sensitive in subsequent infections. However, commercial development of NS1 as a diagnostic tool has revolutionized dengue diagnosis as it has provided simple and low-technology assays that have high sensitivity and specificity. So this audit revealed that the diagnosis had been confirmed after testing positivity with NS1 antigen and IgM antibody which is as per Indian national guidelines for dengue. 29 out of 51 patients were positive with NS1 antigen and 14 patients showed positivity to both NS1 antigen as well as IgM antibody (table no.3).

Management of patients with dengue infections is mainly symptomatic and supportive. There are no specific antiviral drugs for dengue; however fluid replacement therapy for proper maintenance of fluid balance is very crucial and important in management of patients infected with dengue. Infection with Dengue virus can result in four different clinical syndromes. They are undifferentiated fever, the Classic Dengue fever, Dengue Haemorrhagic fever (DHF) and Dengue Shock syndrome (DSS). [9] So Before initiating and planning the clinical management in cases of dengue, it is very important for the clinician to grade the severity of the disease.[10] Grading of the illness according to the severity will not only help the treating physician for

appropriate interventions but also for better outcomes thus reducing the mortality and morbidity. Twenty four patients were in dengue fever without any critical signs and are treated appropriately with careful monitoring of blood pressure, hematocrit, platelet counts on as and when required basis. Antipyretics (Paracetamol) were used along with intravenous fluids (normal saline and ringer lactate) on as required basis. According to the severity of clinical symptoms, Dengue Haemorrhagic Fever is further divided into four grades. Grade I Dengue Haemorrhagic Fever is the presence of easy bruising or a positive tourniquet test in someone with fever, grade II is the presence of spontaneous bleeding into the skin and elsewhere, grade III is the clinical evidence of shock, and grade IV is shock so severe that pulse and blood pressure cannot be detected. Grade III and IV Dengue Haemorrhagic Fever are referred to as Dengue shock syndrome. The presence of thrombocytopenia with concurrent haemoconcentration differentiates Grade 1 and Grade II Dengue Haemorrhagic Fever from Dengue Fever. Nine patients had clinical and hematological features suggestive of grade I Dengue Hemorrhagic Fever (DHF); 9 patients had grade II Dengue Haemorrhagic Fever and 4 patients had grade III Dengue Haemorrhagic Fever and five patients presented directly with grade IV Dengue Haemorrhagic Fever features (table no.4).

4 out 9 patients who presented with Dengue hemorrhagic fever grade I and 3 out of 9 patients who presented with Dengue hemorrhagic fever grade II were inadequately treated with Intravenous fluids (table no.5). For patients with Dengue Haemorrhagic Fever grades III and IV, Immediately after hospitalization, the platelet counts and vital signs should be examined to assess the patient's condition and IV fluid therapy should be started. These patients requires regular and continuous monitoring. All the patients who presented at Dengue Haemorrhagic Fever III and IV stages were treated adequately with Intravenous fluids and the rate of fluid administration was adjusted by frequent assessment of vital signs, urine output and packed cell volumes and this part is compliant with the standard treatment guidelines. All such documentation is evidenced from the case records of patients selected for this audit. Usually the volume of fluid required to be replaced should be just sufficient to maintain effective circulation during the period of plasma leakage.

Platelet count at presentation was more than one lakh in 31 patients and these patients were managed appropriately according to the standard treatment guidelines. Platelet transfusions were not used in any of these patients. In general, there is no need to give prophylactic platelets even at platelet count less than 20,000/mm3. Although the exact platelet count at which platelet transfusions should be given is debatable, prophylactic platelet transfusion may be given at level of platelet count less than 10,000/mm3 in absence of bleeding manifestations. Platelet transfusion may also be given in prolonged shock with coagulopathy and abnormal coagulogram[10]. In case of systemic massive bleeding, platelet transfusion may be needed in addition to red blood cell transfusion. Platelets has been transfused to all patients who had counts less than 10,000 and 3 patients who had platelet counts more than 10,000, but had bleeding manifestations (table no.6). This is as per Indian national dengue guidelines. However few studies state that platelet transfusions have little role in management of dengue patients[11] Transfusion requirements correlate with the occurrence of bleeding in the gastrointestinal system, but not with the platelet counts.[12] Total mortality was evidenced for 2 cases and the cause of death is due to dengue shock syndrome with multi organ failure.

Clinical audit is about measuring the quality of care we provide against relevant standards. If we are failing to meet these standards, the audit should help us understand the factors that are causing us to fail, so that we can set priorities and make improvements.

In our study data was collected retrospectively which we think is the strength of this study.

CONCLUSION:-
Quality control, and consequently the right allocation of resources, is becoming a central issue in the management of Health Care Systems. Several tools are deployed to provide a monitoring of the levels of care and improve its quality. Among them, clinical audit is one of the most popular and widespread. Clinical audit is a quality improvement process that measures current patient care and outcomes against agreed standards of best practice. The comparison between clinical practice and standards leads to the formulation of strategies, in order to improve daily care quality. Diagnosis of the illness and grading the severity of the illness is as per Indian national guidelines for dengue. So

effectively 7 out of 51 (13.68%) patients did not receive fluids therapy as per Indian National Dengue Guidelines. Usage of Inotropes in total 7 patients out of 51 patients is more statistically, specifically usage in Dengue Haemorrhagic Fever grade III is unwarranted if adequate fluid has not been challenged before starting inotropes. Early diagnosis, careful monitoring and proper fluid management goes a long way in reducing the mortality due to dengue hemorrhagic fever and shock syndrome. The final aim of the clinical audit is always improving the care provided to the patient. Clinical audit can be a valuable assistance to any programme which aims to improve the quality of health care and its delivery. Audits and quality improvement projects are vital aspects of clinical governance and continual service improvement in medicine. Clinical audit could offer to the modern clinicians as a useful tool to monitor and advance their clinical practice.

RECOMMENDATIONS:-
* It is desirable to have further research in this area, with a larger sample size.
* Improvements in care implemented as a part of clinical audit must be monitored, evaluated, sustained, and reinforced within a supportive environment.
* Clinical Audit methodology could be potentially extended to several other diseases in the setting of General Medicine and other specialities too.
* Routine clinical audit programmes should be essential components of good clinical and professional practice among all healthcare providers.

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