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RESEARCH ARTICLE

STUDY OF CLINICAL AND EPIDEMIOLOGICAL PROFILE IN PATIENTS OF CEREBRAL VENOUS THROMBOSIS IN A TERTIARY CARE HOSPITAL IN CENTRAL INDIA

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ABSTRACT

Aim: To study clinical and etiological spectrum for early diagnosis and management of CVT. To evaluate factors associated with poor outcome (mRS >2), prognosis and sequelae of CVT at 3 months follow-up. **Methodology:** A Retrospective and prospective observational study performed during 2011-2017 on patients diagnosed of CVT (radiologically confirmed by CTV/MRV) were included. Clinical profile including detailed history, onset, progression, risk factors, etiological spectrum, systemic examination and Routine investigations were done. Neurological status was assessed by mRS and NIHSS. Patients followed-up after 3 months personally/telephonically. Statistical software SPSS used for data analysis. **Results:** MC (52.8%) in young (21-40 years) patients with male preponderance (59.7%) with sub-acute onset (56.9%). MC site were deep sinuses 30 (41.7%) f/b superior sagittal sinus 29 (40.3%). Headache (79.2%) was MC presentation f/b seizures (51.4%). Hyperhomocysteinemia (37.5%) as MC risk factor, OCP use (34.5%) in females and alcohol (46.5%) in males. mRS was not dependent on clinical, etiological and hematological profile. There was significant decrease in mRS and NIHSS on discharge. Altered sensorium, Papilledema, motor deficit, mRS>2, low GCS, high NIHSS, elderly and low calcium predicted poor outcome. Good outcome in (80.56%), poor outcome in (19.4%) and 1 expired. **Conclusions:** CVT is rare treatable cause of stroke with varied presentation and risk factors. MC presentation is headache and seizure; MC risk factor is Hyperhomocysteinemia, OCP, alcohol. CVT has good prognosis if diagnosed earlier and treated promptly.

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INTRODUCTION

Cerebrovenous thrombosis (CVT) is a rare disorder. Early before the introduction of radiological imaging, CVT was only diagnosed after death in autopsy. CVT is responsible for 1-2% of all strokes in adults. It affects all the age groups. The first description of CVT, appearing in the French literature in 1825, was by Ribes in a 45 years old man who died after 6 months history of severe headache, epilepsy and delirium. Incidence of venous thrombosis is less than arterial thrombosis. It is more common in women than in men. This difference may be related to pregnancy or the use of oral contraceptives. There are various risk factors for the development of CVT such as pregnancy, puerperium, systemic diseases, dehydration, OCP and coagulopathies. CVT is a challenging condition because of its variability of clinical symptoms and signs. All the age group can be affected.

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The spectrum of clinical presentation ranges from headache, seizure, papilledema, focal deficit and coma. Before the advent of radiological imaging mortality and morbidity was high and many of the cases remain undiagnosed. But after the advent of CT/MRI/MRV, early diagnosis is easy and appropriate treatment can be started. As the diagnosis is earlier better is the prognosis. Treatment modalities may include anticoagulation or thrombolytic therapy. Anticoagulation therapy include heparin and warfarin. Today CVT is a big therapeutic and diagnostic challenge. As CVT is a rare cause of stroke with highly variable features with heterogeneous predisposing factors, it is needed to study the spectrum of presentations and the spectrum of etiological factors and risk factors, so that with very high level of suspicion we can think about CVT and can diagnose at the earliest and with the help of studying the various risk factors we can think about various causes and can reach the predisposing factor at the earliest, which will be very helpful in the early management of CVT and we can have better prognosis. This study was done in a tertiary center in central India which will help us to know the scenario of CVT in Central India as compared from other parts of the country

and by studying the clinical and etiological spectrum in this region it will help to suspect and diagnose CVT much earlier and consequently better prognosis for the people living in Central India.

Aim: To study the clinical and etiological spectrum for the early diagnosis and management of Cerebrovenous thrombosis.

Objectives

- To identify the spectrum of presentations in patients diagnosed to have CVT.
- To identify the etiological spectrum in the patients diagnosed to have CVT.
- To evaluate factors associated with poor outcome (mRS >2).
- To evaluate prognosis of CVT.
- To evaluate sequelae of CVT at 3 months follow-up.

MATERIALS AND METHODS

Study Design: Retrospective and prospective observational study.

Study Period: One year duration (January 2016 to January 2017).

Study Population: This study was performed in Department of Neurology at a tertiary care centre, on patients hospitalized in between the period (2011 to 2016) with the final diagnosis of CVT confirmed after radiological imaging (CT/MRI/MRV) formed the study population.

Inclusion Criteria

- Patients of any age and gender diagnosed to have CVT confirmed after radiological imaging (CT/MRI/MRV).
- Patient and/or his/her legally acceptable representative willing to provide voluntary informed consent for participation in the present study.

Exclusion Criteria

- Patient and/or his/her legally acceptable representative not willing to provide voluntary informed consent for participation in the present study.

Data collection: All CT scans and MRI were read by an experienced radiologist. Patients were enrolled after radiological confirmation of CVT. The data regarding laboratory tests and radiological investigations were taken through medical records of patients. The data regarding neurological examination for stroke severity and disability scores were collected by the evaluation of patients during admission and follow-up.

MATERIALS AND METHODS

For the prospective cases: Detailed history was taken regarding the mode of onset of initial symptoms, progression and association with any risk factors if present so that we can study various modes of presentation and the risk factors associated them.

With detailed history we can get idea of the etiological spectrum. Systemic examination was done to assess the grade of disability on admission to know the prognosis and outcome at discharge and at follow-up. Routine investigations were done to rule out any metabolic parameters. Also, radiological imaging (CT/MRI/MRV) was done to confirm the diagnosis and to correlate the clinical presentation with the site of thrombosis. Patients were followed-up after 3 months of discharge through in person or telephonic conversation and neurological status was assessed by modified Rankin scale. Those patients who could not be followed after 3 months, their condition at the time of discharge was considered as final diagnosis. Also at admission and discharge NIHSS (National Institute of Health Stroke Scale) was done to quantify the impairment and improvement during discharge

Modified Rankin Scale: It is 6-level outcome scale used to assess level of function in neurological diseases.

mRS -9Q Questionnaire

- Do you have any symptoms that are bothering you? Yes/No
- Are you able to do the same work as before? Yes/No
- Are you able to keep with your hobbies? Yes/No
- Have you maintained your ties to friend and family? Yes/No
- Do you need help making a simple meal, doing household chores, or balancing a check book? Yes/No
- Do you need help with shopping or travelling close to home? Yes/No
- Do you need another person to help you walk? Yes/No
- Do you need help with eating, going to toilet or bathing? Yes/No
- Do you stay in bed most of the day and need constant nursing care? Yes/No

NIHSS (National Institute of Health Stroke Scale): NIHSS tool will be used to quantify the impairment caused by stroke. It is composed of 11 items in which each item is scored a specific ability between 0 and 4. The maximum possible score is 42 and least score is 0.

For the retrospective cases: All the data regarding the clinical presentation, neurological status and findings of radiological imaging were taken from medical records and were assessed. Written permission from Medical Records section was obtained.

Data collection method: A pre-designed customized proforma (Annexure-III) was used for collecting the patient data for both the retrospective as well as the prospective patients.

Outcome measures: Following clinical presentations viz. headache, seizures, altered sensorium, etc. and etiological spectrum viz. dehydration, alcoholism, puerperium, etc. were evaluated.

Statistical analysis: The data from the customized proforma were initially entered into the Microsoft Excel and online statistical software for analysis. The non-parametric association was calculated using Pearson Chi-square test and mean comparisons within the group were done using Paired‘t’ test. A P value of < 0.05 was taken as statistically significant.

Financial considerations: The patients enrolled in the study were managed according to the protocol of the institution. All the tests and procedures that were performed were done according to the institutional protocol. But no additional tests/procedures were done for specific requirement of the study. Hence, there was no additional financial burden on the patient or on the institution. Also present study was not being funded by any pharmaceutical company or institution.

Ethical and medico-legal issues: The synopsis of the present study was submitted to the Ethics Committee and Scientific Review Committee of hospital and after obtaining approval from these two committees, the study was initiated in the institution. No new drug was tested or new procedures were done on these patients. A voluntary written informed consent was obtained from patient and/or his/her legally acceptable representative prior to their enrolment in the study and before conducting any study related procedures. Consent was taken in addition to all the other consents that are routinely taken as per institutional protocol.

RESULTS

The present study aimed at to study the clinical and epidemiological profile of the patients diagnosed to have CVT. Most of the patients were found to be of younger age (21-40 years) (52.8%) with male preponderance (59.7%).Most common mode of onset was sub-acute (56.9%).Most common site of involvement were followed by deep sinuses, 30 (41.7%) followed by superior sagittal sinus, 29 (40.3%). Headache (79.2%) was the most common clinical presentation followed by seizures (51.4%). Hyper-homocysteinemia (37.5%) was the most common risk factor for the development of CVT, whereas considering gender specific risk factors OCP use (34.48% females) was common in females and alcohol (46.5% males) was common in males. Conventional risk factors like puerperium (2.8%) and pregnancy (2.8%) were uncommon. Motor deficit was present in 22 (30.56%) in which 11 (50%) patients had mild deficit, 5 (22.7%) had moderate deficit and 6 (27.3%) had severe deficit. Considering the pattern of occupation most patients in the study had lifestyle of moderate activity (72.2%).Anemia was found in 16 (22.2%) patients in which 5 (6.9%) had mild anemia, 7 (9.7%) had moderate anemia and 4 (5.6%) had severe anemia. Polycythemia was present in only 2 (2.8%) patients. mRS on follow up was not dependent ($P > 0.05$) on Clinical spectrum like fever, headache, seizure, aphasia, nuchal rigidity, diplopia and involvement of multiple cranial nerves at presentation. Also, mRS on follow up was not dependent ($P > 0.05$) on etiological spectrum like Hyperhomocysteinemia, alcohol consumption, anemia, dehydration, OCP use, infection, pregnancy, puerperium, polycythemia and deep leg vein thrombosis or unknown etiology. mRS at follow up was also not associated with seasonal variation, lifestyle (sedentary, or moderator vigorous activity), hematological profile like mean Hb, mean total leukocyte count, mean platelets and metabolic parameters like mean sodium level (Na), mean potassium, mean Creatinine level, mean BUN level, mean SGOT, mean SGPT, mean bilirubin level and mean uric acid level. There was significant decrease ($P < 0.05$) in mean mRS at follow up (0.75±1.40) as compared to mean mRS at admission (1.90±1.45) and there was significant decrease ($P < 0.05$) in NIHSS on discharge (0.76±2.76) as compare to NIHSS on admission (1.35±3.88) implying good outcome. Mean mRS at admission for good mRS (<2) at follow-up was 1.28 ± 0.69 and for poor mRS (>2) at follow-up was 4.50 ± 0.52. The difference was statistically significant ($P<0.05$), showing that mean mRS at admission was higher in poor mRS in comparison to good mRS at follow-up. Mean GCS score for good mRS (<2) at follow-up was 14.71 ± 1.11 and for poor mRS (>2) at follow-up was 10.07 ± 3.32. The difference was found to be statistically significant ($P<0.05$), showing that mean GCS score was higher in good mRS in comparison to poor mRS at follow-up. Altered sensorium, Papilledema, motor deficit, mean mRS>2 on admission, elderly age of presentation, low GCS on admission, high NIHSS on admission, and among the metabolic parameters low calcium level were found to be the predictors of poor outcome.Most of the patients had good outcome (80.56%) and less patients had poor outcome (19.4%) and 1 patient expired (1.39%).

DISCUSSION

The present study involved 72 patients in which 43 (59.7%) were males and 29 were females (40.28%) showing male preponderance similar to other studies but most of the studies showed female preponderance in which most study showed the cause of female preponderance to be puerperium and use of OCP. Reason for male preponderance nowadays may be because of decreasing incidence of CVT due to puerperium as a risk factor and due to better obstetric health care and increasing consumption of alcohol. Most common age group involved was between 21-40 (52.8%) years, may be because of use of OCP in this age group by females and more alcohol consumers are at this age group. Most common mode of onset was sub-acute in 41 (56.9%) patients as in previous studies. Most common site of thrombosis was deep sinuses followed by superior sagittal as it was found in previous studies but in many studies superior sagittal was more common.

Clinical spectrum: In our study also it was found that most common presentation was headache (79.1%) similar to the above study and previous studies. Among 72 patients 57 (79.1%) presented with headache as the initial presentation followed by seizures which was present in 37 (51.39%) patients followed by papilledema which was present in 28 (38.8%) patients, fever in 14 (19.4%), aphasia in7 (9.7%)patients, diplopia in 4 (5.6%), nuchal rigidity in 6 (8.3%), altered sensorium in 13 (18.1%), focal neurological deficit in 22 (30.5%) from which 11 (50%) were mild, 5 (22.7%) were moderate, 6 (27.27%) were severe. Narayan *et al* (2012) studied 428 patients in which the spectrum of clinical presentation was very large and patient presented with various symptoms and signs similar as in our study such as headache (88.3%), vomiting (69.6%), seizure (39.9%), fever (5.14%), diplopia (27.5%), drowsiness in (12.8%) patients, hemiparesis in (23.8%), in which most common presentations were headache, vomiting, seizures, fever.

Etiological spectrum: Out of 72 patients 27 patients (37.5%) were having Hyperhomocysteinemia as a risk factor which was also found in many previous studies. Out of 29 females 10 females (34.48% females) were OCP users who were diagnosed to have CVT. So if patient who is an OCP user presents with persistent headache or any stroke like symptom, CVT should not be overlooked. 11 (15.28%) patients were having dehydration as risk factor. Out of 43 male patients 20 (46.51% males) were alcoholic. 4 (5.56%) patients were having infection considered to be the cause of CVT in which 2 had viral meningitis and 2 had malaria.

0	**No symptoms**
1	No significant disability, able to carry out all usual activities despite some symptoms
2	Slight disability, able to look after own affairs without assistance, but unable to carry out all the previous activities
3	Moderate disability, requires some help but able to walk unassisted
4	Moderately severe disability, unable to attend to own bodily needs without assistance and unable to walk unassisted
5	Severe disability, requires constant nursing care and attention, bedridden, incontinent
6	Dead

The NIHSS scoring will be done according to the following table

Score	Stroke Severity
0	No Stroke Symptoms
1-4	Minor Stroke
5-15	Moderate Stroke
16-20	Moderate to Severe Stroke
21-42	Severe Stroke

Table 1. Distribution of CVT patients according to Clinical Presentations(N=72)

Clinical Presentation	Number	Percentage (%)
Headache	57	79.2
Seizures	39	51.4
Papilledema	28	38.9
Motor deficit	22	30.6
Fever	14	19.4
Altered sensorium	13	18.1
Aphasia	7	9.7
Nuchal rigidity	6	8.3
Diplopia	4	5.6
Multiple cranial nerve palsies	1	1.4

Table 2. Distribution of CVT patients according to Etiological Spectrum(N=72)

Etiological Spectrum	Number	Percentage (%)
Hyperhomocysteinemia	27	37.5
Alcohol	20	27.8
Anemia	16	22.2
Unknown	12	16.7
Dehydration	11	15.3
OCP	10	13.9
Infection	4	5.6
Pregnancy	2	2.8
Puerperium	2	2.8
Polycythemia	2	2.8
Deep leg vein thrombosis	0	0.0

Table 3. Comparison of various study parameters in relation to Mean mRS at follow-up

StudyParameters	Mean mRS at follow-up		t test	p value
	Good Outcomen = 58 Mean ± SD	Poor Outcomen = 14Mean ± SD		
Age (years)	36.1 ± 13.0	44.7 ± 14.2	-2.19, df=70	0.032*
Serum Calcium Level	9.11 ± 0.38	8.84 ± 0.46	2.26, df=70	0.027*
Mean mRS at admission	1.28 ± 0.69	4.50 ± 0.52	-16.25, df=70	0.000*
GCS score	14.71 ± 1.11	10.07 ± 3.32	8.93, df=70	0.000*
NIHSS score	0.38 ± 1.04	8.00 ± 5.51	-10.03, df=70	0.000*

Table 4. Comparison of Mean mRS and Mean NIHSS at admissionand at follow-up

StudyParameter	At admission	At follow-up	't' Value	P value
	Mean ± SD	Mean ± SD		
Mean mRS	1.90 ± 1.45	0.75 ± 1.40	17.07, df=69	0.000*
Mean NIHSS	1.86 ± 3.95	0.93 ± 2.68	3.43, df=71	0.001*

Out of 29 female patients 2 patients (6.89% females) were in puerperium and 2 patients (6.89% females) were pregnant indicating that conventional risk factors are becoming less common. Considering the occupation it was found that CVT was more commonly found in patients with moderate activity who were 52 (72.2%) in number, and then in patients with sedentary lifestyle who were 19 in number (26.39%) and only 1 (1.39%) patient had CVT with vigorous activity.

Considering systemic diseases 16 patients (22.2%) were found to be anemic in which 5 patients (6.94% of total patients) were mildly anemic, 7 patients (9.2%) were moderately anemic and 4 (5.56%) were severely anemic. 2 (2.78%) patients had polycythemia. Narayan *et al*. (2012) studied 428 cases in which common risk factors identified were anemia in 79 (18.4%), Hyperhomocysteinemia in 78 (18.2%), alcoholism in 67 (15.6%), oral contraceptive pill (OCP) intake in 49 (11.4%),

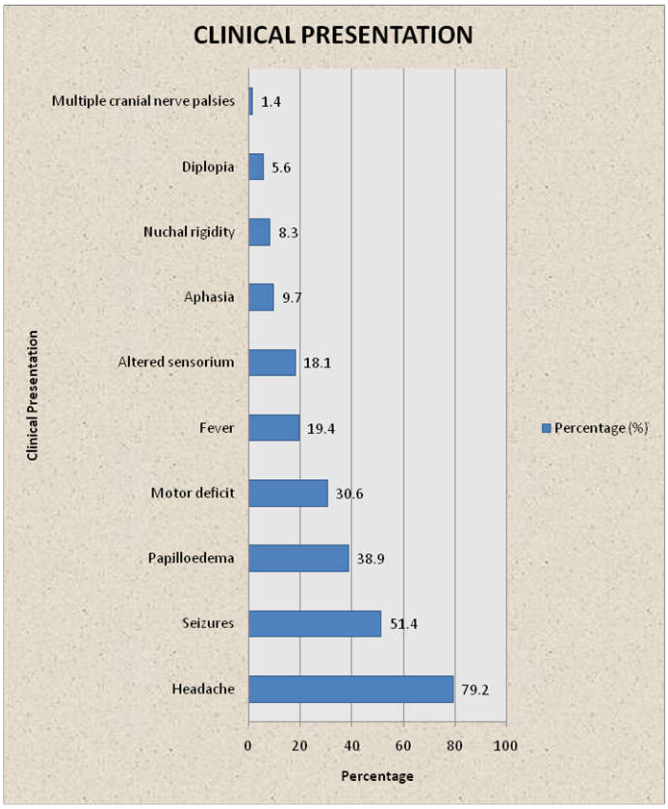

Figure 1. Bar diagram showing distribution according to clinical presentation

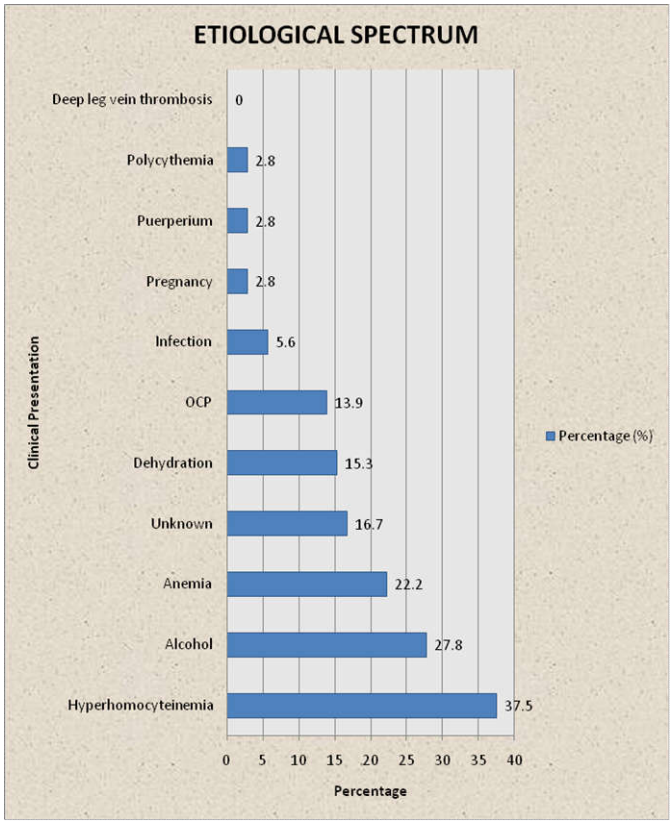

Figure 2. Bar diagram showing distribution according to etiological spectrum

postpartum state in 42 (9.8%), anticardiolipin antibodies in 31 (7.2%), and protein S deficiency in 53 (12.3%) patients. Multiple risk factors (two or more) were seen in 78 (18.2%) patients. No risk factor could be identified in 69 (16.1%) patients.

These were similar to our study and other previous studies. Salehi *et al*. (2016) studied the seasonal pattern of CVT and concluded that incidence of CVT was more in high temperature than cold temperature, but in our study it was found that 31 (43.06%) patients were found to have CVT in summer season, 31 (43.06%) patients in winter and 10 (13.89%) patients in rainy season which indicated that there was not much variation in the incidence of CVT with respect to temperature which is different from the previous study. There were 12 (16.67%) patients with unknown cause. Multiple risk factors (2 or more than 2) were involved in 29 (40.28%) patients of CVT. Among the metabolic parameters it was found that low calcium level was associated with 29 (40.28%) patients in whom 4 (5.55%) patients had isolated hypocalcaemia without any other risk factor. None of study to our knowledge till date has been done to show the correlation between serum Calcium level and development of CVT, though it has been mentioned in the studies that low serum calcium level can be associated with ischemic stroke. From our study also it was concluded that there are various risk factors which can lead to the development of CVT as they were present in previous studies and along with the mentioned risk factors some deranged metabolic parameters (Low Calcium Level) were also found to be present in the patients of CVT, Other metabolic parameters studied were within normal limits in almost all the patients.

Factors associated with poor outcome: In our study all the clinical, etiological and metabolic parameters were studied for the association with poor outcome of the patients having CVT. Over all there were 14 (19.4%) patients who had poor outcome (mRS>2).The significant prognostic variables which were associated with poor outcome found in our study were:

- **Presence of altered sensorium at the time of presentation:** In our study it was found that 13 (18.05%)patients presented with altered sensorium in which 6 (46.1%) of them came out with poor outcome which was statistically significant (P value=0.007)
- **Papilledema:** In this study it was found that out of 72 patients 28 (38.8%) patients had papilledema at presentation in which 12 (42.8%) out of them had poor outcome which was statistically significant (P value=0.000).
- **Presence of neurological motor deficit:** 22 patients had motor deficit out of which 11 (15.3%) were mild, 5 (6.9%) was moderate and 6 (8.3%) were severe, which was statistically significant (P value=0.000).
- **Mean Baseline mRS>2 on admission:** It was found that that higher mRS on admission (4.5 ± 0.52) was associated with poor outcome at follow up which was statistically significant (P value=0.000).
- **Mean age group:**In our study elder patients (44.7 ± 14.2 years) had poor outcome as compared to younger patients (36.1 ± 13) which was statistically significant (P value=0.032), as in previous studies.
- **Mean GCS on admission:** Mean GCS on admission was low (10.07 ±3.32) in the patients with poor outcome which was statistically significant (P value=0.000)
- **Mean NIHSS on admission:** Mean NIHSS score was high (8 ± 5.51) in the patients with poor outcome at follow up which was statistically significant (P value=0.000)

- **Mean calcium level:** In our study it was found that among the metabolic parameters patients having low calcium levels (8.84± 0.46) was associated with poor outcome after 3 months follow up which was statistically significant (P value=0.027).Rao *et al* (2016) studied 30 patients in which 4 (13.33%) patients had poor outcome, Among the 4 patients who has an mRS score of >2 on 3 months follow up, 3 (75%) had diagnostic delay of more than 10 days, 3 (75%) had stupor/ coma at admission, 3 (75%) had papilledema, 4 (100%) had hemorrhage on CT / MRI, 4 (100%) had thrombosis of straight sinus and / or deep venous system. Other previous studies also showed that papilledema, altered sensorium, involvement of deep sinus, low GCS on admission were predictors of poor prognosis (66.67.69.70). In our study also there were many similar findings.

Prognosis of CVT: In our study it was found that after 3 months follow up 58 (80.56%) patients had good outcome (mRS <2) on follow up in which 54 patients (75%) had mRS on follow up turned out to be zero.., suggestive of good prognosis of CVT after treatment. Out of 72 patients 71 (98.6%) patients were managed conservatively with heparin and anticoagulation in which 58 (81.7%) had good outcome (mRS <2 at follow up), and 13 (18.3%) had poor outcome (mRS >2 at follow up) but all of them were alive, but 1 (1.38%) patient underwent decompressive surgery along with conservative medical management and she was also improving neurologically but died due to respiratory arrest (blockage of endotracheal tube).so overall it can be said that now a days CVT has good prognosis which can be attributed to the high level of suspicion, better investigation modalities, early diagnosis and prompt treatment. Patil *et al* (2014) their study showed that 84% of patients had good outcome after treatment with heparin followed by anticoagulants. Zuluaga *et al* (2015) their study showed 92% patients had favorable outcome on follow up. Yadegari *et al*. (2016) showed that 84% patients had good outcome and study done by Rao *et al*. (2016) showed that 76.6% patients had good outcome on follow up.

Sequelae of CVT at 3 months follow-up: Out of 72 patients 50 (69.4%) had mRS <2 on admission and 22 (30.56%) patients had mRS >2 on admission. 1 (1.39%)patient expired during the hospital course only (her mRS on admission was >2), So only 71 patients could be followed up after 3 months of which 50 patients (70.4%) whom mRS was <2 on admission had good outcome on follow up also after treatment. From remaining 21 patients whom mRS was >2 on admission 13 (61.9%) patients had poor outcome (mRS >2) on 3 months follow up and 8 (38.09%) patients had good outcome (mRS<2). So over all after 3 months follow up from 71 patients 58 (81.6%)patients had good outcome and 13 (61.9%) had poor outcome but all were alive. In our study we have considered alcoholic to a person who consumes more than 140 gm. of alcohol per week and OCP, if used for more than 1 month continuously.

Declaration of conflict of interest: No potential conflicts of interest relevant to this article were reported.

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