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Outcome of Cerebral Venus Sinuses Stenting on Idiopathic Intracranial Hypertension

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ABSTRACT

Background: Raised intracranial pressure [ICP] without any defined clinical or radiological signs of space-occupying intracranial lesions and with normal cerebrospinal fluid [CSF] examination is characterized as idiopathic intracranial hypertension [IIH]. We aimed to assess the venous sinus stenting effectiveness in the IIH treatment.

Patients and Methods: This case control study was conducted on 10 patients with IIH. The subjects were categorized into two groups [one control group and one study group] both matched in in demographics. The control group: received traditional IIH treatment for three months, while the study group received traditional IIH treatment, as well as undergoing venous sinus stent for three months. All patients were subjected to full neurological and general examination, detailed neurological and medical history, and headache disability assessment and Headache Impact Test [HIT-6] questionnaire.

Results: In the stent group, there was an improvement in the papilledema level as follows; two [20%] patients reach normal fundus examination, 2 [40%] patients with papilledema grade I, 1[20%] with grade II and. The headache [HIT] score also improved to 59.3 without any reported other type of headache. We found a right transverse sinus [TS] attenuation in three patients and left TS attenuation in two patients. There was an improvement in the CSF pressure by 9.8±1.3 mmH2O. Also, there was improvement in the radiological findings in the form of absence of that Empty Sella, tortuous veins, and flatting of the globe.

Conclusion: All of our patients have benefited from and responded to stenting quite well, with positive outcomes. Numerous investigations have shown that there are no intraoperative problems after venous stenting for IIH.

Keywords: Intracranial Pressure; Intracranial Hypertension; Stenting

INTRODUCTION

Raised intracranial pressure [ICP] without any defined radiological or clinical signs of space-occupying intracranial lesions and with normal cerebrospinal fluid [CSF] examination is recognized as idiopathic intracranial hypertension [IIH]. Men contribute about 9% of all confirmed cases of IIH. However, it is an uncommon disease among young children and the elderly. Female patients with a body mass index over 30 kg/m^2 and who are at childbearing age are considered to be typical IIH patients. Patients who are considered atypical IIH are males or females with BMI under 30 kg/m^2 [1-5].

Headache is the most frequent complaining symptom in up to 84% of patients with IIH. Vision disturbances are the second most typical symptoms. However, the most distinct sign of cerebral hypertension is papilledema. The Frisén scale has been employed in clinical practice to grade papilledema [6].

The diagnostic criteria of IIH included a cut-off opening pressure of >25 cm CSF, increased optic nerve tortuosity, flattened posterior globe/ sclera, enlarged optic nerve sheath [perioptic subarachnoid space], intraocular protrusion of the optic nerve head, the cerebro-venous sinuses attenuation of the bilateral transverse sinuses [TS] or dominant TS stenosis. The imaging modalities used for diagnosis of IIH include Magnetic resonance venography [MRV] and magnetic Resonance Imaging [MRI]] [7].

In the space-occupying absence or obstructive lesion, elevated ICP manifestations are required for the diagnosis. Additionally, a normal composition of the CSF and an elevated ICP with documentation are required [7].

Wall *et al.* [8] updated diagnostic criteria for IIH set as upper 250 mmH_2O. However, to make sure there are no further underlying causes, these patients need further deep investigations. Patients with the clinical picture of definite IIH without papilledema are considered to have the unusual variant of IIH called IIH without papilledema. It is crucial to look for characteristics like sixth nerve palsy and MRI characteristics indicate increased ICP. In addition, ocular remission with resolution of the papilledema is another a typical type of IIH [9]. Recently, there is a considerable debate about elevated ICP. Uni- or bilateral cerebral sinus stenosis, which is present in nearly all IIH patients and confirmed by MRV. TS stenosis is the most commonly identified type [10].

Since the stenosis clears itself when ICP is reduced and is therefore believed to be due to the elevated ICP, the relationship between both IIH and sinus stenosis is still under debate [2]. In some patients, stenosis is cleared when intracranial pressure is lowered in some patients only and not all patients, which raise the debate whether stenosis is a consequence or a cause for idiopathic intracranial hypertension [11].

According to studies, stenting of venous sinus has just lately come into the picture as a possible therapy option for IIH. It is a secure and efficient method to lower ICP and relieve symptoms [11].

In this trial, we sought to determine if stenotic sinus segment stenting had a beneficial impact on IIH with headache and papilledema.

PATIENTS AND METHODS

This prospective case control study was conducted, as a pilot study, on 10 patients with IIH who were admitted to the local University Hospitals from September 2022 to December 2022. They were chosen on the word of The Modified Dandy Criteria to Diagnose II. All cases provided a written informed consent prior the participation in the study. In addition, the local ethical committed approved the conduction of this trial.

Exclusion criteria were age ≤ 18 years, creatinine more than 1.5 mg/dL, presence of any contraindications to general anesthesia, severe allergic reaction to iodine contrast, aspirin usage, anticardiolipin syndrome or thrombophilic disorder, anticoagulants or clopidogrel, pregnancy, other arteriovenous lesion affecting cortical venous flow or dural arteriovenous fistula, and malignant hypertension.

Included subjects were categorized into two groups [study and control group] both matched for demographics and degree of disability, who were undergoing the same medical treatment but with change of dose according to the body weight. The control group [n=5] received traditional IIH treatment for three months, while the study group [n=5] received traditional IIH treatment, in addition to undergoing venous sinus stent [VSS] for three months.

If cases had one or more of the following, they were considered for VSS as they were intolerant or refractory to standard medical therapy. These included failed prior surgical management, persistent, progressive, or vision threatening papilledema, intractable headaches, and other raised ICP symptoms in spite of maximal medical therapy.

All patients were subjected to full neurological and general examination [to secondary causes of raised ICP], detailed neurological and medical history, headache disability assessment calculated by the Headache Impact Test [HIT-6] questionnaire, and ophthalmology examination including [visual acuity, pupil examination, visual fields, unilateral or bilateral sixth nerve palsy assessment, fundus examination for Grading of papilledema according to Frisen scale].

All patients with papilledema underwent lumbar puncture [LP] to assess the opening pressure after receiving normal imaging. In the lateral decubitus posture, all of the patients began the examination. The pressure recording took place with the case rested and their legs stretched after the needle had been placed into the CSF space. Before taking the reading, the CSF level had time to stabilize.

Venous Sinus Stenting: Sheath 8 fr was inserted in the vein, Bern diagnostic catheter over the wire to reach the venous sinuses, Diagnostic photo with injection of dye in the sick sinus syndrome till reaching both sigmoid sinuses. Intermediate catheter [SOFIA [Soft torque able catheter optimized for Intracranial Access; Micro-Vention, Aliso Viejo, California, USA] or Catalyst] was used to measure the pressure difference before and after the stenosis. A general anesthetic was utilized throughout the operations. A minimum of five days prior to the procedure, dual antiplatelet therapy [clopidogrel 75 mg and aspirin 100 mg] was initiated. A French sheath of six or eight was positioned in the jugular bulb above a wire in order to gain access to the femoral vein. Heparin was administered intravenously to elevate the activated clotting time beyond 250 s. The procedure commenced with the bolus administration of 3000 heparin units, which was subsequently followed by an hourly infusion of 1000 heparin units. The sheath contained a microcatheter, which was inserted into the superior sagittal sinus via a 0.014-inch guidewire. To determine the pressure gradient across the stenotic area, pressures were measured at multiple locations, including the superior sagittal sinus, torcular, pre-stenotic TS segment, and post-stenotic TS or sigmoid sinus. Afterward, general anesthesia, the balloon angioplasty catheter was placed across the stenosis and dilatation occurred subsequent to the exchange of the microcatheter. Following the balloon angioplasty completion, a self-expanding stent was inserted across the stenotic segment of the superior sagittal sinus using a rigid 0.018-inch guidewire. Subsequent to the stent insertion, the trans-stenosis gradient was detected by passing the microcatheter through the stent to the level of the torcular. A single antiplatelet agent [either 75 mg of clopidogrel or 100 mg of aspirin] was prescribed for life if there was no contraindication, following the continuation of dual antiplatelet therapy for 3 to 6 months following stenting.

MRV, headache and papilledema evaluations were performed on all selected patients three months later. The headache assessment was conducted utilizing the HIT-6 questionnaire, and the papilledema evaluation was performed utilizing the Frisen scale.

Statistical analysis: All data were analyzed utilizing Statistical Package for the Social Sciences [SPSS] 28 [SPSS Inc., Armonk, IL, USA, 2020]. The normality Data distribution was tested utilizing the Kolmogorov–Smirnov test. Quantitative data were displayed as mean ± Standard deviation [SD]. Qualitative data were displayed as frequencies and percentages. Groups were compared by appropriate tests according to type and distribution of data. In addition, values before and after treatment were compared by paired tests. P value < 0.05 was considered significant.

RESULTS

Five patients were included in each group. The average age in the stent group was 33.4 years while in the medication group was 35 years old. All of them were females. BMI is comparable among groups [32.2 kg/m^2 in the stent group and 34.8 kg/m^2 in the medications group]. For the past medical history, the stent group was free except for one patient with hypertension, while in the medication group, there was one patient [20%] with hypertension, 2 [40%] with cataract, and the other one [20%] with a thyroid problem.

On history taking the stent group reported that 2 of them start the clinical presentation with headache and other three patients with visual problems. Three of them reported rapid course of progression and 2 with slight slower course. In the medication group, one of patients started the clinical presentation by headache, another one with visual problems and the others 3 patients

had both headache and visual problems. Two of them reported rapid course of progression while other three with slight slower course. In the stent group, the mean Hit score was 65.8 with no signs of 6th nerve palsy. Two [40%] patients with papilledema grade I, and another 2 [40%] with grade III and one [20%] with grade IV [Data not tabulated].

Before treatment, both groups were comparable regarding hit score and CSF pressure. However, there was significant difference between groups after treatment. In the stent group, hit score significantly reduced after than before stenting and similarly CSF pressure significantly reduced after than before stenting. However, the change in medication group was statistically non-significant [Table 1].

Regarding the radiological examinations, we discovered that in the stent group, Empty Sella was present in two cases [40%] and tortuous veins in one case. Additionally, the globe was flattened in two cases [40%] as well. In the treatment group, we discovered that Empty Sella appeared in two cases [40%], tortuous veins in one patient [20%], and flattening of the globe appeared in two cases as well [40%] all together. Two patients [40%] had left TS attenuation and three patients [three] had right TS attenuation as one patient with bilateral TS attenuation in this group.

After three months, by reducing the venous pressure gradient, which is believed to promote CSF absorption and lower ICP, venous sinus stenosis stenting has become an effective method of alleviating IIH symptoms. In the stent group we found improvement in the papilledema level as follows; two [20%] patients reach normal fundus examination, 2 [40%] patients with papilledema grade I, 1[20%] with grade II and. The HIT score also improved to 59.3 without any reported other type of headache. Also, there was improvement in the radiological findings in the form of absence of that Empty Sella, tortuous veins, and flatting of the globe. We found a right TS attenuation in three patients and left TS attenuation in two patients. There was an improvement in the CSF pressure by 9.8±1.3 mmH_2O. One patient had grade I papilledema, three had grade II, and one had grade III in the treatment group, however none of the patients were able to undergo a normal fundus examination. The HIT score in medication group without any improvement 67.4 in comparison to the stent group [**Figures 1 and 2].**

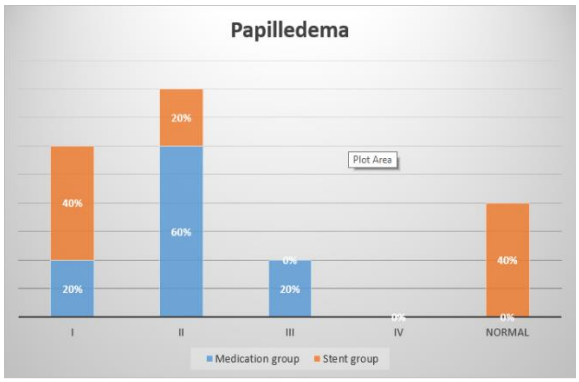

Figure [1]: After 3 months follow up of papilledema

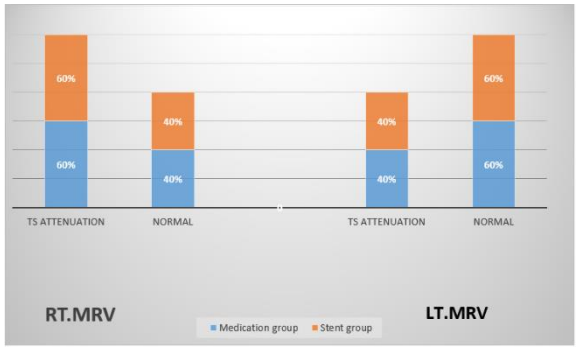

Figure [2]: After 3 month's radiological follow-up

In figures 3 and 4, we presented a female patient, aged 45 years old, neither diabetic nor hypertensive. She is married and has three kids. Headaches that would suggest more icteric interference with daily duties and were connected to visual haze first appeared 1.5 years ago as a symptom of the disorder. After six months, she sought medical help, and an examination revealed papilledema. Every two months, she was admitted to the hospital with pressures ranging from 35 to 50 cm hg for LP withdrawal. Right transverse and sigmoid sinus stenosis was detected by MRV **[Figure 3]**. The papilledema [from grade III to normal fundus] and HIT score [from 70 to 60] improved after three months of follow-up after the patient had stenting **[Figure 4]** off the stenotic sinuses and administered cidamax 250 mg twice daily for three months.

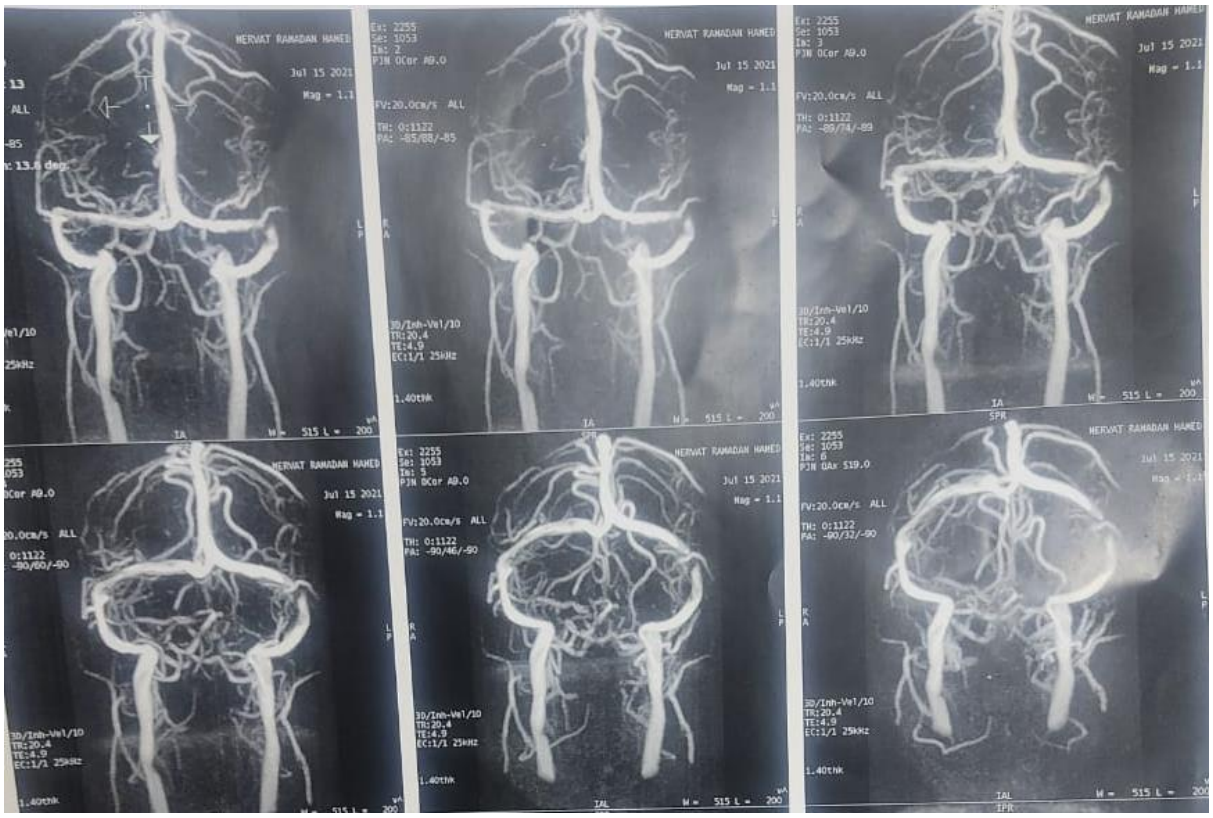

Figure [3]: Preoperative MRV showed focal stenosis of right transverse sinus

Figure [4]: Casper stent 7-40 was inserted with good restoration of the flow

Table [1]: Comparison between both groups as regard HIT score and CSF pressure

		Time regarding treatment		P
		Before	After	
Hit score	Stent group	65	59.3	<0.001*
	Medication group	64.8	67.4	0.654
Paired comparison [p value]		0.378	<0.001*	
CSF Pressure [mmH2O]	Stent group	37	27.1	<0.001*
	Medication group	39.6	38.2	0.798
Paired comparison [p value]		0.455	<0.001*	

DISCUSSION

The radiological examination of suspected cases is focused on ruling out recognized causes of elevated ICP because IIH is partially classified as a disorder with an uncertain etiology [12].

There are several risk factors connected to the emergence of IIH. Obesity and gender are two important risk factors, although little is known about the real IIH pathophysiology.

According to **Smith *et al.*** [13], this has given rise to several hypotheses, including endocrinological causes [abnormalities in parathyroid hormone or adrenocorticotropic hormone, and excessive growth hormone consumption], nutritional causes related to vitamin A metabolism [retinoid usage or hyper-vitaminosis A], with decrease intracranial venous drainage obstruction or CSF absorption.

A fraction of individuals with stenosis in dural venous sinus, frequently in the transverse-sigmoid sinus junction, have been identified during first neuroimaging with computed tomography veno-graphy or MRV and may benefit from venous stenting. Bilateral transverse-sigmoid sinus stenosis, unilateral transverse-sigmoid sinus with aplasia or contralateral hypoplasia and localized superior sagittal sinus stenosis are among the IIH subset patients that are most likely to benefit [14].

Since cerebral venous stenosis is increasingly identified as an IIH etiology, dural VSS has become a potentially helpful treatment. Recent research has revealed promising clinical results in terms of the disappearance of headaches and tinnitus, the papilledema decrease, and the improvement of visual function. Visual acuity and visual field are two objective measurements of ophthalmologic outcomes that have been made available in more recent data. In order to support the dural venous sinus stenting usage to enhance vision in IIH individuals, more rigorous ophthalmologic data was required in upcoming trials [15].

In our trial, we sought to determine if the stenting of stenotic sinus segment was beneficial for treating IIH accompanied by headache as well as papilledema at the local University Hospitals, we conducted a comparative study on two matched groups of patients who had a confirmed diagnosis of IIH. The patient group received traditional treatment for IIH along with a VSS for 3 months, whereas the control group only received traditional treatment for IIH for those 3 months.

Matching our Smith *et al.* [13] conducted a case study of 17 patients 15 female]. The average age was 29.47 years [21–39]. BMI ranged from 24.54–46.18 kg/m^2 [mean 35.24 kg/m^2]. LP at opening pressure ranged from 26–55 cmH_2O [mean = 38.1 cmH_2O; n = 17]. All of them were treated by a stent.

In the present study, the radiological data showed improvement by being free of that empty Sella, tortuous vines, and globe flattening. Two patients experienced right TS attenuation, while three patients experienced left TS attenuation. Forty-three percent [43%] of patients who got stent installation. In the trial by **Sheilds *et al.*** [12] documented a cessation of their headache symptoms during the trial. A total of twenty-two patients [52.4%] maintained treatment for migraines or other types of persistent headaches. At least 71.5% of IIH patients, according to the authors, exhibited migrainous symptoms, including photophobia-phonophobia and nausea. The large proportion of individuals who continue to experience headaches after obtaining a stent could be clarified by the similarity between the headaches connected to chronic migraines and IIH. The headaches following stent implantation might have been caused by increased ICP; however, TS stenosis was not a factor.

The mean follow-up LP opening pressure in patients, as determined by **Smith *et al.*** [13], varied between 12 and 34 cmH_2O [mean = 22.4; n = 9]. This change was found to be statistically significant utilizing the paired t-test [p = 0.0027; 95% confidence interval: -25.11 to -7.55]. The transverse-sigmoid sinus junction was stenotic in every patient, with most cases affecting the right side. Prior to and following the intervention, the pressure gradients were recorded as 23.06 [13–41] and 1.18 mmHg [0–5], respectively. The mean pressure gradient [MPG] analysis before and after the intervention revealed a statistically significant difference [p< 0.001]. To evaluate the effectiveness of stenting, they employed more objective outcome measures such as visual acuity, peripapillary retinal nerve fiber layer [RNFL] thickness, and visual fields. Additionally, the patients were monitored for a duration of 12 months [13].

A computed tomography venogram that was performed six months following surgery and revealed that every patient had a patent stent was used to corroborate this discovery. In addition, after having the stent treatment, most of the patients' papilledema disappeared, showed its efficiency [13].

According to a trial by **Higgins *et al.*** [16], between 17% and 100% of patients experienced a headache remission following this therapy.

A group of 13 patients underwent dural VSS [DVSS] therapy in 2010 showed improvements in their headaches and papilledema [17]. Visual function of all cases except one case and the headaches in 7 cases improved after receiving DVSS, according to a study from 2013 [2].

Based on the literature analysis of 40 patients from 2009, 83% experienced headache relief, 75% were treated for papilledema, and 20% had optic atrophy [18]. In our opinion, a greater MPG treatment threshold increases the specificity for identifying patients who would benefit from stenting. Following the stent procedure, we did not find any complications.

In a trial by **Sheilds *et al.*** [12], they noted many problems, involving subdural hemorrhage, venous sinus perforation, in-stent thrombosis, stent migration, and far from the stent or recurrent stenosis immediately proximal development, following this treatment. Due to disease stenosis and progression either close to or far from the first stent, two cases required re-stenting. The second stent was implanted in these individuals one or two years later after the first stent, respectively. The probability of undergoing a second stenting procedure may be reduced by using a longer stent during the initial surgery [12].

It is determined whether to continue with DVSS following dural sinus manometry and cerebral venography. The neuro-interventionist determines the MPG thresholds, which range from 4 to 10 millimeters of mercury and, in our cases, are above 15 millimeters. The stenting procedure is based on the fluid dynamics and CSF absorption of the dural sinuses. Usually, pressures are raised close to stenosis. Stenting normalizes intrasinus pressures and encourages CSF absorption, which lowers ICP. Although, there are several possible interpretations for these findings. The venous sinuses compliant walls are prone to deformation when under pressure. Stenting group is more effective than medication group as regard improvement in HIT score and CSF pressure.

Study limitation

A major limitation of the current work is the small number of patients included in each group. This prevents the globalization of results, warrants cautious treatment of these results and future studies with a high number of patients is highly recommended.

Conclusions

All of our patients have benefited from and responded to stenting quite well, with positive results. Numerous investigations have shown that there are no intraoperative problems after venous stenting for IIH. We advise that in order to settle the long-term efficacy of VSS implantation in IIH individuals, more randomized controlled trials are required. Endovascular intervention is more likely to become the acknowledged care standard for carefully chosen patients as endo-vascular technology and our understanding of the underlying IIH processes develop.

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