Fifty shades of gradients: does the pressure gradient in venous sinus stenting for idiopathic intracranial hypertension matter? A systematic review

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OBJECTIVE The role of venous sinus stenting (VSS) for idiopathic intracranial hypertension (IIH) is not well understood. The aim of this systematic review is to attempt to identify subsets of patients with IIH who will benefit from VSS based on the pressure gradients of their venous sinus stenosis.

METHODS MEDLINE/PubMed was searched for studies reporting venous pressure gradients across the stenotic segment of the venous sinus, pre- and post-stent pressure gradients, and clinical outcomes after VSS. Findings are reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

RESULTS From 32 eligible studies, a total of 186 patients were included in the analysis. Patients who had favorable outcomes had higher mean pressure gradients (22.8 ± 11.5 mm Hg vs 17.4 ± 8.0 mm Hg, $p = 0.033$) and higher changes in pressure gradients after stent placement (19.4 ± 10.0 mm Hg vs 12.0 ± 6.0 mm Hg, $p = 0.006$) compared with those with unfavorable outcomes. The post-stent pressure gradients between the 2 groups were not significantly different (2.8 ± 4.0 mm Hg vs 2.7 ± 2.0 mm Hg, $p = 0.934$). In a multivariate stepwise logistic regression controlling for age, sex, body mass index, CSF opening pressure, pre-stent pressure gradient, and post-stent pressure gradient, the change in pressure gradient with stent placement was found to be an independent predictor of favorable outcome ($p = 0.028$). Using a pressure gradient of 21 as a cutoff, 81/86 (94.2%) of patients with a gradient > 21 achieved favorable outcomes, compared with 82/100 (82.0%) of patients with a gradient ≤ 21 ($p = 0.022$).

CONCLUSIONS There appears to be a relationship between the pressure gradient of venous sinus stenosis and the success of VSS in IIH. A randomized controlled trial would help elucidate this relationship and potentially guide patient selection.

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KEY WORDS idiopathic intracranial hypertension; venous sinus stenting; pseudotumor cerebri; venous stenosis; pressure gradient; interventional neurosurgery

IDIOPATHIC intracranial hypertension (IIH) is a relatively uncommon, poorly understood headache syndrome that is often difficult to treat. The diagnostic criteria involve symptoms and signs of raised intracranial pressure (ICP) in the absence of any mass lesion or other identifiable cause. Additionally, there must be a documented elevation of pressure and normal CSF composition.²⁴ Female sex and obesity are the only proven associations with IIH.

Multiple diseases and medications have been implicated but any definitive association has never been conclusively proven.³

Management of IIH involves protection of optic nerve function and control of symptoms. In the absence of severe, rapidly progressive vision loss, a stepwise approach is typically implemented with lifestyle modifications (diet and weight loss where appropriate) and medical manage-

ABBREVIATIONS BMI = body mass index; ICP = intracranial pressure; IIH = idiopathic intracranial hypertension; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; VSS = venous sinus stenting.

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FIG. 1. PRISMA flow diagram. Figure is available in color online only.

ment (stopping potential offending agents or starting acetazolamide) comprising the first line of treatment. Refractory cases may require surgical intervention in the form of CSF diversion or optic nerve sheath fenestration.⁸ In a small subset of patients, venous sinus stenting (VSS) may be an option, particularly in those who fail to respond to other therapies. Selection of patients with IIH who may benefit from VSS is problematic. One approach is to use venous sinus manometric pressure measurements taken on either side of the stenotic segment and stent those patients with an “elevated” pressure gradient. In this study, we systematically review the literature to establish whether a higher pressure gradient across the stenosis is associated with an improved outcome following stent placement.

Methods

Review Methodology

This systematic review followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A systematic literature search (registered in 2017 in PROSPERO [no. CRD42017058126], an

international database of prospectively registered systematic reviews: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017058126) was conducted in MEDLINE/PubMed with the following search terms: stenting, pseudotumor cerebri, idiopathic intracranial hypertension, and benign intracranial hypertension. We included studies published in English before March 2017 that reported the pre- and post-stent pressure gradients of every patient (not simply the mean of the group) undergoing VSS for IIH, where individual postoperative clinical outcomes could be identified (Fig. 1). Two authors (C.M.M. and V.S.B.) independently reviewed the abstracts and full papers where relevant. The reference lists of full-text and review articles were also reviewed to identify additional relevant publications.

Data Collection

Pressure gradients reported in centimeters of water were converted to millimeters of mercury. Outcomes were based on visual parameters (if reported) as well as clinical symptoms (headache). We categorized outcomes as “wors-

TABLE 1. Patient demographics and pressure gradient measurements grouped by outcomes

Outcome	Unfavorable			Overall Comparison* (p value)	Favorable			ANOVA Tests† (p value)
	Overall	Worsened	Unchanged		Overall	Improved	Resolved	
No. of patients (%)	22 (11.8%)	4 (2.2%)	18 (9.7%)	NA	164 (88.2%)	117 (62.9%)	47 (25.3%)	NA
Age (yrs)	34.1 ± 8.8	28.5 ± 7.0	36.3 ± 8.7	0.87	35.2 ± 12.5	35.2 ± 12.3	35.1 ± 13.0	0.75
Sex‡	21 F (95.5%), 1 M	4 F (100%), 0 M	17 F (94.4%), 1 M	0.47	129 F (87.8%), 18 M	93 F (93.0%), 7 M	36 F (76.6%), 11 M	0.02
BMI	34.3 ± 8.1	29.2 ± 0.0	35.4 ± 8.7	0.84	34.8 ± 8.3	36.0 ± 7.9	32.9 ± 8.6	0.23
CSF opening pressure (cm H ₂ O)	34.3 ± 6.8	34 ± 1.4	34.3 ± 7.6	0.27	43.6 ± 27.7	45.5 ± 32.6	39.1 ± 7.9	0.49
Pressure gradients (mm Hg)	17.4 ± 8.0	11.0 ± 6.3	18.8 ± 7.7	0.033	22.8 ± 11.5	23.6 ± 12.3	20.8 ± 9.1	0.042
Post-stent gradients (mm Hg)	2.7 ± 2.0	2.3 ± 1.5	3.0 ± 2.4	0.934	2.8 ± 4.0	2.9 ± 4.2	2.5 ± 3.3	0.937
Change in pressure gradient (mm Hg)	12.0 ± 6.0	8.8 ± 4.8	13.2 ± 6.2	0.006	19.4 ± 10.0	19.9 ± 10.9	18.5 ± 8.1	0.031

NA = not applicable.

All data given as means ± SDs, unless otherwise indicated. Only available patient-level data were included.

* Comparison between overall values in each group (unfavorable and favorable).

† Comparison of mean pre-stent gradients, mean post-stent gradients, and pressure gradient changes between the individual outcomes (worsened, unchanged, improved, and resolved).

‡ Data on sex were not available for 17 patients (9.1%).

ened,” “unchanged,” “improved,” or “resolved.” “Worsened” or “unchanged” outcomes were considered “unfavorable” while “improved” or “resolved” outcomes were considered “favorable.” If there was discordance between the resolution of headaches and the ocular symptoms, the outcome was considered “improved” but not “resolved.” Additionally, permanent but stable visual field deficits were considered improved or resolved depending on the resolution of headache symptoms.

Most studies measured and listed the gradients directly across the stenosis. One study listed the gradients between the torcular herophili and the jugular bulb before and after stenting.²² In this case the difference between the 2 overall gradients was used to approximate the actual gradient across the stenosis.

Statistical Analysis

Categorical variables were compared using Pearson’s chi-square test. Continuous variables were compared using the Student t-test and ANOVA where appropriate. Multivariate stepwise logistic regression analysis was performed to identify independent predictors of favorable outcomes. All p values were 2-tailed, with an α of 0.05. Statistical analysis was performed using SPSS (version 20, IBM Corp.).

Results

We identified 186 patients treated with VSS from 32 studies in which both the pressure gradients across the stenosis as well as the clinical outcomes were reported for patients individually (Fig. 1).^{2,6,7,10–16,18,19,21–23,25,28,29,31–39,42–44} As a group, the venous pressure gradients across the stenotic segments ranged from 2 to 77 mm Hg with a mean of 22.1 mm Hg. The mean duration of clinical follow-up

was 18.3 months. There were only 22 patients (11.8%) with an unfavorable outcome.

The results are summarized in Table 1. The conditions of 4 patients (2.2%) were worse following stent placement, 18 patients (9.7%) were unchanged, 117 patients (62.9%) improved, and 47 patients (25.3%) experienced full resolution of symptoms. The mean pressure gradients in the “favorable” groups were higher than those of the “unfavorable” groups (22.8 ± 11.5 mm Hg vs 17.4 ± 8.0 mm Hg respectively, $p = 0.033$). The 2 groups’ mean post-stent pressure gradients were not significantly different (2.8 ± 4.0 mm Hg vs 2.7 ± 2.0 mm Hg, respectively, $p = 0.934$). However, the change in pressure gradients after stent placement was higher in the “favorable” groups (19.4 ± 10.0 mm Hg) compared with the “unfavorable” groups (12.0 ± 6.0 mm Hg, $p = 0.006$).

ANOVA tests comparing the mean pre-stent gradients, mean post-stent gradients, and pressure gradient changes between the individual outcomes (worsened, unchanged, improved, and resolved) showed statistically significant differences in the patients’ pre-stent gradients ($p = 0.042$) and pressure gradient changes ($p = 0.031$) but not their post-stent gradients ($p = 0.937$).

In a multivariate stepwise logistic regression controlling for age, sex, body mass index (BMI), CSF opening pressure, pre-stent pressure gradient, and post-stent pressure gradient (Table 2), the change in pressure gradient with stent placement was found to be an independent predictor of favorable outcome (improvement/resolution of symptoms, $p = 0.028$).

Using a pressure gradient of 21 as a cutoff, 81 (94.2%) of 86 patients with a gradient > 21 achieved favorable outcomes, compared with 82 (82.0%) of 100 patients with a gradient ≤ 21 ($p = 0.022$). Following stent placement, a change in pressure gradient ≥ 18 resulted in favorable

TABLE 2. Multivariate stepwise logistic regression analysis of predictors of favorable outcomes after VSS for IIH

Variable	OR	95% CI	p Value
Change in pressure gradient	1.39	1.04–1.85	0.028
Age	NA	NA	0.218
Sex	NA	NA	0.771
BMI	NA	NA	0.641
CSF opening pressure	NA	NA	0.457
Pressure gradient	NA	NA	0.239
Post-stent gradient	NA	NA	0.403

CI = confidence interval; OR = odds ratio.

outcomes in 79 (97.5%) of 81 patients compared with 65 (83.3%) of 78 in those in whom the change in pressure gradient was < 18 ($p = 0.0023$).

Discussion

The idea that the correction of a venous pressure gradient across a stenotic segment of venous sinus would alleviate the underlying cause of symptoms in IIH is appealing. The “gradient theory” offers not only a plausible pathophysiological explanation for IIH but also provides a desperately needed objective measure to guide patient selection for VSS. Current endovascular balloon and stent technology provides a low morbidity option to achieve this goal.

Venous Sinus Stenosis and IIH

Whether venous sinus stenosis is the primary problem or occurs secondary to elevated ICP is debated. Sinus stenosis in IIH appears to be exceedingly common. Using specific MRI sequences, Farb et al. identified the presence of bilateral venous sinus stenosis in more than 93% of patients with IIH compared with 7% of control subjects. They subclassified 2 types of stenosis: focal stenosis and a more tapered, or smooth, stenosis over a longer segment of the involved sinus. These investigators noted that both types of stenosis could theoretically be part of IIH pathophysiology.¹⁷ Kumpe et al. speculated that there might be a difference in outcomes between these 2 groups following VSS.²⁸

Several studies have attempted to characterize the stenosis following IIH treatment that did not involve VSS. Bono et al. described an unchanged venous sinus stenosis over time in 14 patients with IIH, 9 of whom were successfully medically treated with normalization of the ICP. No patient underwent manometry.⁵

Other authors have noted dynamic changes in the degree of stenosis. King et al. found that venous pressure gradients could be lowered by removing CSF and effectively lowering the ICP, but radiographic change in the stenosis was not studied.²⁷ Rohr et al. also demonstrated reversible venous stenosis in 3 patients, again without manometry.³⁸ Notably, none of these investigations incorporated all 3 parameters (radiological findings, manometry, and ICP).

In one of the most extensive studies to date, Levitt et al.

evaluated 155 patients who underwent venous sinus manometry and found that patients with a diagnosis of IIH had a 35% incidence of having an elevated venous pressure gradient, which they defined as > 8 mm Hg. Importantly, they also found that no patients in their study with normal ICP had an elevated venous pressure gradient.³⁰

Rationale for a Pressure Gradient Threshold

Despite the overwhelmingly positive outcomes published in the literature, there does not appear to be a push to embrace VSS as a “first-line” therapy in IIH. Instead, the focus has shifted to identifying patients with IIH refractory to other treatments who are most likely to benefit from VSS. The majority of patients with IIH are managed medically and thus only a subset of patients ever undergoes transvenous catheterization. Reports for many series to date include experience with stent placement, but the processes used for selection and screening of the patients in the VSS treatment group are often unclear.^{22,28,35}

In their series, Albuquerque et al. placed stents in 18 patients based solely on the presence of radiographic venous sinus stenosis. Although the authors did not incorporate this procedure into the treatment algorithm, they did measure the pressure gradients across the stenosis and defined a “significant” gradient as greater than 12 mm Hg. Albuquerque et al. noted that 70% of patients with a “significant” gradient were clinically improved. While not specifically discussed by the authors, of the 8 patients without a “significant” gradient, 4 were clinically improved following stenting (50%).¹

In a review of all published cases to date, Starke et al. identified 185 cases treated with VSS. Overall, 78% of patients had improvement in headaches while 86% of patients had improved vision (although not all studies reported visual outcomes).⁴¹ Although their review included studies that did not report venous pressure gradients, Starke et al. calculated a mean overall venous pressure gradient of 20 mm Hg that resolved to 4.4 mm Hg after stent placement. They stated that in addition to stenosis “there must also be physiologic evidence of a significant pressure gradient across the stenosis in order for stenting to be clinically efficacious.”⁴¹ What constitutes a “significant” gradient is not mentioned.

All studies included in our review measured venous sinus manometric pressure to establish a pressure gradient across a narrowed portion of the sinus in every patient. This approach, albeit with different sinus pressure thresholds for treatment, resulted in a favorable outcome in 88.2% of patients. Although this percentage is impressive given the often refractory nature of IIH symptoms, it is unclear whether this represents an improvement in outcome from simply placing stents in all patients with stenosis, or a reporting bias. Nevertheless, using the venous pressure gradient to try and define a group of patients who are more likely to benefit from VSS necessitates the selection of a threshold gradient above which stenting would be considered.

Setting the Bar

Although derived from a small sample size, the normal

physiological gradient from the superior sagittal sinus to the jugular bulb has been reported to be between 0 and 3 mm Hg.²⁷ It should be noted that sinus pressures can also fluctuate with changes in ventilation. Kumpe et al. noted that sinus pressure measurements were frequently (but not always) decreased in patients under general anesthesia compared with measurements in the same patients while awake.²⁸

Many authors selected thresholds at or around 10 mm Hg.^{1,22,28,34} The basis for this cutoff may be derived from the experience of skull base surgery. Spetzler et al. described safely sacrificing a unilateral sigmoid sinus to improve surgical exposure of jugular bulb lesions if the sinus pressure at the time of temporary surgical occlusion remained below 10 mm Hg.⁴⁰ Ziyal et al. reported that sacrifice of the sinus is safe if the pressure does not rise more than 5 mm Hg from its baseline following temporary occlusion.⁴⁵

Although a cutoff around 10 mm Hg was common, there was wide variation between studies. Radvany et al. used gradients of > 4 mm Hg as an indication for treatment and reported improved or resolved outcomes in 92% of patients (although the average gradient in this series was still 12 mm Hg).³⁶ Goodwin et al. also used a cutoff of > 4 mm Hg for stenting and found improved outcomes in 83% of patients.²⁰ Fields et al. selected a cutoff of > 10 mm Hg and found an 87% rate of improved outcome.¹⁹

In their review, Teleb et al. found a mean pressure gradient of 18.5 mm Hg. Notably, only 7 of 22 studies included in their review reported manometry findings. Though they do acknowledge the lack of available data regarding VSS in this patient population, they suggest a pressure gradient of ≥ 8 mm Hg as a strict requirement for stent placement.⁴²

At this time there is no widespread consensus on a pressure gradient threshold on which to base the decision to place a stent or not. Our results incorporate the largest volume of available data from published studies to date and suggest that there is a positive association between improved clinical outcomes and increasing transvenous pressure gradients. However, the size of the gradient at which this becomes true is likely higher than previously thought.

Our data suggest a significant decrease in the chances of a positive outcome once the change in gradient following VSS drops below 18 mm Hg. Thus, patients with pressure gradients ≥ 21 are very likely to benefit from VSS while those with gradients < 21 should undergo more careful consideration prior to VSS.

Limitations of the Study

Selection bias in this study was probable because the gradients of all the patients examined in this review were relatively high (mean 22.1 mm Hg) and thus the prevalence of successful outcomes in the majority of patients predominantly represented the treatment of those patients with “significant gradients” at the outset. Several authors did mention patients who underwent endovascular manometry and were not treated because of insufficient gradients, while other authors reported placing stents in all patients with stenosis.^{1,6,19} In some studies, no patients were found to have lower gradients. Donnet et al. had a

minimum gradient of 14 mm Hg and a mean of 29 mm Hg.¹⁴ It is possible that careful clinical and radiological patient selection somehow filters out patients with a lower pressure gradient who may be less likely to benefit from VSS, thus leading to a high rate of positive outcomes, but the relationship between patient selection and manometric findings has yet to be clearly defined. Additionally, publication bias of positive outcomes from VSS is also likely.

The pharmacological and physiological effects of anesthesia on cerebral venous sinus pressures appear to be somewhat variable but generally tend to lower the pressures.²⁸ Thus, the gradients used in our study may be artificially low. Ninety-eight patients (53%) reviewed in this study underwent venous manometry while awake prior to stent placement under general anesthesia. We therefore cannot completely control for this variable.

Another consideration is the potential for variability in the stenosis itself and thus the pressure gradient across it. Multiple authors have described changes or even complete resolution of stenosis and pressure gradients following CSF drainage and lowering of the ICP.^{9,26} Indeed, this observation is part of one theory regarding the etiology of IIH in which a vicious cycle of increasing ICP leads to venous sinus stenosis. This then creates worse venous drainage and CSF resorption, further exasperating increases in ICP.⁴ In this scenario, a stent might be placed when the pressure gradient is at or near its nadir but still serves to prevent dynamic collapse, thus avoiding entrapment in such a cycle.

Finally the amount of available clinical follow-up was different in each study and between individual patients in most series. Changes in clinical conditions over time (improvement or worsening) could potentially affect the results of this study.

Conclusions

VSS for IIH appears to have good clinical results in selected cases. From the available reported cases in the literature there appears to be a correlation between an increasing pressure gradient across the region of stenosis and the chances of an improved outcome. However, there is currently no agreement on the definition of what constitutes a pathologically elevated pressure gradient or the conditions under which that gradient is obtained. This study underscores the need for prospective, randomized studies of VSS for IIH. To date, 1 pilot study has been completed³¹ and 1 randomized trial has not yet begun recruiting (NCT02513914; clinicaltrials.gov).

Appendix

Electronic Search Strategy

((("pseudotumor cerebri"[MeSH Terms] OR ("pseudotumor"[All Fields] AND "cerebri"[All Fields]) OR "pseudotumor cerebri"[All Fields] OR ("idiopathic"[All Fields] AND "intracranial"[All Fields] AND "hypertension"[All Fields]) OR "idiopathic intracranial hypertension"[All Fields]) OR ("pseudotumour cerebri"[All Fields] OR "pseudotumor cerebri"[MeSH Terms] OR ("pseudotumor"[All Fields] AND "cerebri"[All Fields]) OR "pseudotumor cerebri"[All Fields])) OR ("pseudotumor cerebri"[MeSH Terms] OR ("pseudotumor"[All Fields] AND "cerebri"[All Fields]) OR "pseudotumor cerebri"[All Fields]) OR "benign"[All Fields] AND "intracranial"[All Fields] AND "hypertension"[All

Fields)) OR “benign intracranial hypertension”[All Fields])) AND (“stents”[MeSH Terms] OR “stents”[All Fields] OR “stenting”[All Fields]).

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Disclosures

Dr. Pride reports being a consultant to Sequent Medical. Dr. Welch reports being a consultant for Stryker Neurovascular, receiving royalties for product design from Peter Lazic, Inc., and working as a proctor for Covidien.

Author Contributions

Conception and design: McDougall, Beecher, Pride, Welch. Acquisition of data: McDougall, Ban. Analysis and interpretation of data: McDougall, Ban, Beecher, Welch. Drafting the article: all authors. Critically revising the article: McDougall, Pride, Welch. Reviewed submitted version of manuscript: McDougall. Approved the final version of the manuscript on behalf of all authors: McDougall. Statistical analysis: Ban. Administrative/technical/material support: McDougall, Welch. Study supervision: Pride, Welch.

Supplemental Information

Previous Presentations

Portions of the work were presented in poster form at the Society of Neurointerventional Surgery Conference in Boston, Massachusetts, July 25–29, 2016.

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