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ORIGINAL RESEARCH

How Effective Is Endovascular Intracranial Revascularization in Stroke Prevention? Results from Borgess Medical Center Intracranial Revascularization Registry

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EDITOR'S CHOICES

BACKGROUND AND PURPOSE: The WASID study established the risk of subsequent ischemic stroke at 1 year in subjects with symptomatic intracranial atherosclerotic stenosis (70%–99%) at 18%. The efficacy of different methods of endovascular revascularization in stroke prevention still has not been established. We compared the stroke rate in our registry at 1 year following intervention with the WASID results to identify which method, if any, provides the most benefit in stroke prevention. This result from the BMC-IRR follows a previously published article comparing stent placement and angioplasty outcomes.

MATERIALS AND METHODS: We maintained a nonrandomized single-center single-operator registry of consecutive symptomatic patients who underwent endovascular intracranial revascularization. Data were collected prospectively and retrospectively and analyzed retrospectively. Patients were treated with angioplasty, BMS, or self-expanding WS. To make our data comparable with that in the WASID study, we selected patients with a single lesion of 50%–99% stenosis undergoing a single intervention. Data was collected on patients until symptom recurrence, repeat intervention, or 1 year postintervention, whichever occurred first.

RESULTS: We found that 115 patients fit the inclusion criteria, with 38 angioplasty, 28 BMS, and 49 WS cases. For patients with 70%–99% stenosis, the overall probability of stroke at 1 year postintervention was 19.3%. The overall stroke probability per device, independent of clinical presentation, was 12.5% for angioplasty, 20.2% for BMS, and 24.1% for WS.

CONCLUSIONS: Compared with the WASID data, angioplasty appears to have a lower stroke rate after 1 year than medical therapy alone. However, neither stent-placement arm compared favorably with the WASID results.

ABBREVIATIONS: ACA = anterior cerebral artery; BA = basilar artery; BCC-IRR = Borgess Medical Center Intracranial Revascularization Registry; BMS = balloon-mounted stent; BMT = best medical therapy; CI = confidence interval; ICA = internal carotid artery; MCA = middle cerebral artery; mRS = modified Rankin Scale; SAMMPRIS = Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis; SSYLVIA = Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries; TIA = transient ischemic attack; VA = vertebral artery; WASID = Warfarin-Aspirin Symptomatic Intracranial Disease; WS = Wingspan stent

Despite the presence of numerous studies in the literature addressing intracranial angioplasty and stent placement in patients with symptomatic intracranial atherosclerotic disease, it is still not clear whether any of these modalities are an acceptable alternative to medical therapy alone. This is predominately due to the fact that for a long time, the probability of stroke in this patient population was not clearly documented. This all changed with the publication of the WASID study,[1] which established stroke risk in this population in a prospective randomized fashion. The intracranial revascularization series published before the WASID study had no clear reference against which to measure its efficacy,[2-9] and the newer series are retrospective and concentrate on reporting complication rates following intervention and/or the stroke rates during the follow-up period.[10-25] None of these series are prospective, and they do not report the probability of stroke within 1 year of intervention as in the WASID study. Furthermore, the comparisons reported in the literature between angioplasty, the BMS, and the WS (Boston Scientific, Natick, Massachusetts) were insufficient because various investigators compared their complication rates using a specific device with what was reported in the literature by other operators using different techniques at different times and sometimes using different devices.

We are reporting here a subgroup of patients from our prospective intracranial revascularization registry with characteristics (demographics, clinical presentations, risk factors, and lesion distributions) similar to those in the WASID study population. Using the same statistical analysis that was used in the WASID study, we compared the stroke probability after 1 year for all treatment methods (angioplasty, BMS, and WS)

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with their reported stroke probability. We hope that this direct comparison of the 3 available devices will shed further light on the merit in stroke prevention of each device compared with medical therapy alone.

Materials and Methods

Study Design and Subject Eligibility

The study design was presented in detail in a prior publication.[26] The BMC-IRR was designed as a nonrandomized single-center single-operator data base of consecutive symptomatic patients with intracranial arterial stenosis who underwent endovascular revascularization. The registry protocol was approved by the local institutional review board, and all subjects gave consent for the intracranial revascularization procedure. The Borgess Research Institute received approval of the institutional review board to waive informed consent for data collection and analysis. Data were entered prospectively and retrospectively in a secure outcome data base (MD Analyze, Medtech Global, www.medtechglobal.com) and were analyzed retrospectively. Subjects were included in the registry if they were ≥40 years of age and presented with TIA or stroke that was attributable to angiographically verified ≥50% arterial stenosis. Exclusion criteria were contraindication to aspirin or clopidogrel bisulfate (Plavix). The protocol called for a follow-up catheter angiography at 3 months (6 months for drug-eluting stent) and an office visit at 1 year; mRS was repeated each time.

To make the comparison with the WASID study results, we selected patients from our registry with a single lesion of 50%–99% stenosis undergoing a single intervention. Patients were removed from data collection when a stroke occurred, when a second intervention was performed for any reason (recurrent symptoms and/or significant restenosis), or when the 1-year mark was passed. All ischemic strokes occurring during the observation period (periprocedural up to 1 year postintervention) were included in our analysis. If angioplasty alone failed to dilate the vessel to ≤50% stenosis, the intervention was counted as a technical failure but the intervention was included in the results. Angioplasty was followed by stent placement when large flow-limiting dissection occurred. For the purpose of this article, if complications occurred during that intervention, the case was counted in the angioplasty arm (analysis of complications based on intention to treat).

Major versus Minor Stroke

Strokes occurring during the first year following the intervention were classified as major or minor on the basis of the change in mRS score; a change of ≤1 classified the stroke as minor, while changes of ≥2 indicated a major stroke.

Vessel Groups

In our statistical analysis, we grouped the intracranial vessels with perforators (MCA and BA) separately from the vessels without perforators (VA and the ICA).

Statistical Analysis

For the purpose of the analysis and due to the relatively small sample size, we grouped all stent-placement cases together and compared them directly with the angioplasty arm. We performed a stroke probability analysis at 30 days and again at 1 year.

For our comparison with the WASID to be more statistically sound, we chose an α value of .05, knowing that we would lose differences that may have been found at the .10 level. We also ceased collecting data on our patients at 1 year or if they had >1 lesion or >1 intervention, to stay consistent with the WASID analysis. The WASID analysis did involve a z score analysis, whereas we used a χ^2 analysis because our software program was SAS (SAS Institute, Cary, North Carolina). According to our statisticians, the results provide minimal difference in interpretation and little-to-no difference in determining significance.

The statistical methods used in our analysis were the Cox proportional hazards modeling, the Pearson χ^2 test, the Cochran-Mantel-Haenszel test with odds ratios, the Kaplan-Meier method, and descriptive statistics.

Table 1: Patient demographics and medical history

	No. of Patients with Data (%)[a]	Stroke in Territory (%) (n = 20)	No Stroke in Territory (%) (n = 95)
Age (yr)	115	64.05 ± 11.8	66.1 ± 12.9
Sex			
Male	68 (59)	8 (12)	60 (88)
Female	47 (41)	12 (26)	35 (74)
Diabetes			
No	60 (57)	9 (15)	51 (85)
Yes	46 (43)	8 (17)	38 (83)
Hypertension			
No	13 (12)	1 (8)	12 (92)
Yes	96 (88)	19 (20)	77 (80)
Hyperlipidemia			
No	31 (28)	7 (23)	24 (77)
Yes	78 (72)	12 (15)	66 (85)
Ischemic stroke			
No	49 (57)	9 (18)	40 (82)
Yes	37 (43)	5 (14)	32 (86)
Heart disease			
No	72 (69)	15 (21)	57 (79)
Yes	32 (31)	4 (13)	28 (88)
Smoking			
No	41 (63)	6 (15)	35 (85)
Yes	24 (37)	4 (17)	20 (83)

[a] Data are not available for all patients.

Results

Of the 140 consecutive subjects who underwent intracranial endovascular revascularization between April 2002 and January 2009, 115 subjects fit the criteria of a single lesion (50%–99% stenosis) undergoing a single intervention. The subject demographics, medical history, clinical presentation, lesion characteristics, and intervention type are described in Tables 1 and 2. One of the lesions in the angioplasty arm was in the ACA, and we excluded this case from the analysis because it was the only lesion in the ACA.

Twenty-four subjects had a complication within the first 30 days, 17 due to stroke and 7 for other reasons (2 required a second intervention, 3 were lost to follow-up, and 2 died). Three more strokes occurred after the first 30 days (day 78, day 174, and day 230). The total number of strokes encountered within the first year was 20 (17.4%). Most of these strokes (85%) occurred within the first 30 days, and 40% were major, while 60% were minor.

At 30 days, angioplasty was significantly safer than stent placement (P = .031) and smooth lesions were safer than irregular lesions (P = .049). Female sex and the number of days

Table 2: Patient presentation, intervention, and lesion characteristics

	No. of Patients with Data (%)[a]	Stroke in Territory (%) ($n = 20$)	No Stroke in Territory (%) ($n = 95$)
Days from last symptom to treatment	115	32.8 ± 34.3	66.2 ± 124.2
Treatment			
Angioplasty	38 (33)	4 (11)	34 (89)
BMS	28 (24)	5 (18)	23 (82)
WS	49 (43)	11 (22)	38 (78)
Presenting mRS at time of intervention	115 (100)	1.8 ± 1.3	1.4 ± 1.1
% Stenosis before primary procedure			
<70%	7 (6)	1 (14)	6 (86)
≥70%	107 (94)	19 (18)	88 (82)
Qualifying event			
TIA	39 (34)	8 (21)	31 (79)
Minor stroke	28 (25)	7 (25)	21 (75)
Major stroke	46 (41)	5 (11)	41 (89)
Lesion location			
ICA/VA	46 (40)	6 (13)	40 (87)
MCA/BA	68 (60)	14 (21)	54 (79)
Lesion morphology			
Smooth	80 (72)	12 (15)	68 (85)
Irregular	31 (28)	8 (26)	23 (74)
Concentric	58 (52)	9 (16)	49 (84)
Eccentric	53 (48)	11 (21)	42 (79)
Ulceration	17 (15)	4 (24)	13 (76)
No ulceration	94 (85)	16 (17)	78 (83)
Lesion length			
Short (<5 mm)	44 (40)	5 (11)	39 (89)
Moderate (5–10 mm)	17 (15)	5 (29)	12 (71)
Long (>10 mm)	50 (45)	10 (20)	40 (80)
Activated clotting time at stent deployment	85 (74)	216.2 ± 32.5	217.0 ± 24.9
Time from 1st visit until event (day)	115 (100)	25.9 ± 63.3	269.5 ± 133.2

[a] Data are not available for all patients.

from presentation to intervention were only marginally associated with greater risk but were not statistically significant ($P = .062$ and $P = .066$, respectively). On the basis of the analysis at 1 year, angioplasty was marginally safer than stent placement ($P = .052$). The remaining variables were not significant predictors of unfavorable outcome (Table 3).

The overall estimated stroke probability at 1 year in our subject population, independent of clinical presentation, degree of stenosis, and type of intervention, was 19%.

However, when we stratified subjects by clinical presentation (TIA versus stroke), subjects who presented with only TIA fared better with 12% probability of stroke a year after the intervention compared with 26% for subjects who presented with stroke (Table 4). This trend became even more apparent when we further stratified the stroke at presentation as minor versus major, with 21% and 32% chances of stroke, respectively (Table 5). Because 94% of our patients had ≥70% stenosis, we think that our data are not suited to assess the significance of increases in the degree of stenosis when calculating stroke probability.

When we compared the probability of stroke at 1 year postintervention, based on the device used, angioplasty had the lowest probability (12.5%) compared with either stent, with 19% for the BMS and 24% for the WS, despite not being statistically significant (Table 6).

To test whether the relative safety of angioplasty, compared with stent placement, was due to the vessel selected for treatment, we examined the outcomes in terms of the device used and the vessel group involved in the treatment; the data showed that angioplasty is still safer than stent placement, regardless of the vessel involved (Table 7). Furthermore, the WS group and the angioplasty group had very similar lesion distributions, with the exception of the BA in the WS arm (Table 8).

Discussion

The WASID study established several points: The risk of stroke is highest during the first year after presentation, and risk for stroke increases with increasing vascular stenosis and severity of clinical presentation.[1] This is in agreement with our findings because subjects who presented with TIA had better outcomes than subjects presenting with stroke, and most of our patients (94%) had significant (≥70%) stenosis at presentation. Overall stroke risk in the WASID study was 11% at the end of the first year, but when stroke risk was stratified by the degree of vascular stenosis and clinical presentation, the risk of stroke in the same timeframe varied significantly. In patients presenting with stroke and ≥70% stenosis, the probability of stroke recurrence at 1 year was 23%. If a patient presented with TIA and the lesion stenosis was 50%–69%, the probability of stroke recurrence dropped to 3% (Table 4).[27] The probability of stroke for all symptomatic (TIA or stroke) patients with vascular stenosis of ≥70% was almost 18% at the end of the first year.[25] This identified a specific group of patients with high stroke-recurrence risk. The SAMMPRIS study was subsequently launched to assess the efficacy of intracranial stent placement for stroke prevention in symptomatic patients with ≥70% vascular stenosis by using the WS system plus BMT in comparison with BMT alone.

We believe that the comparison between our registry and the WASID data is valid. Our data were collected prospectively and retrospectively, and our subjects have demographics similar to those in the WASID subject population. Furthermore, our clinical presentation and lesion distribution were almost identical to that of the WASID population (Table 9). We also used the same statistical analysis performed in WASID to allow us to compare our stroke probability.[1]

As with the WASID study, our results demonstrate that presenting symptoms have a significant impact on the probability of subsequent stroke. This appears to be true not only when we compare TIA with stroke (Table 4) but also when we compare minor-versus-major stroke as presenting symptoms (Table 5).

Our overall point estimate of the 1-year rate of stroke at 19% is very close to the 18% estimated stroke risk in patients in WASID,[1] and both are very close to the SSYLVIA[28] estimated stroke risk at 1 year. These findings call into question the merit of intracranial revascularization in stroke prevention.

However, on closer examination, different devices used had different point estimates of stroke rate at 1 year. The estimated risk of stroke in the angioplasty arm was the lowest at 12.5% at 1 year. The WS group had the highest, at 24.1% at 1

Table 3: Probability of stroke based on symptom recurrence or repeat intervention at 30 days and 1 year

	30 Days		1 Year	
	Significant *P* Value	95% Hazard Ratio CIs	Significant *P* Value	95% Hazard Ratio CIs
Stenting vs angioplasty	.031	0.010–0.799	.052	0.041–1.016
Female vs male	.062	0.940–12.280	.133	0.776–6.838
Minimal vs maximum no. of days from symptom onset to treatment	.066	0.399–1.030	.218	0.527–1.157
Smooth vs irregular lesion	.049	0.085–0.995	.074	0.128–1.099
Concentric vs eccentric lesions	.121	0.121–1.278	.287	0.200–1.611
Medium/long vs short lesions	.145	0.709–10.442	.193	0.680–6.756

Table 4: Probability of stroke in the territory based on presenting severity of stenosis and qualifying event[a]

	Stenosis 50%–99%	Stenosis 50%–69%		Stenosis 70%–99%	
Qualifying Event	BMC-IRR	BMC-IRR	WASID	BMC-IRR	WASID
TIA (1 yr)	0.11 (0.05–0.25)	0	0.03 (0.01–0.06)	0.12 (0.05–0.26)	0.14 (0.06–0.22)
Stroke (1 yr)	0.25 (0.16–0.38)	0.20 (0.03–0.80)	0.08 (0.04–0.12)	0.26 (0.16–0.40)	0.23 (0.15–0.30)

[a] Data are presented as mean probability (95% CI).

Table 5: Probability of stroke in the territory based on presenting severity of stenosis and qualifying event: TIA, minor stroke, or major stroke[a]

	Stenosis 50%–69%	Stenosis 70%–99%
TIA		
1 year	0	0.116 (0.050–0.256)
Minor stroke		
1 year	1.000	0.212 (0.106–0.400)
Major stroke		
1 year	0	0.322 (0.166–0.566)

[a] Data are presented as mean probability (95% CI).

Table 6: Probability of stroke within 1 year in the territory based on intervention type[a]

	Stenosis 50%–99%	Stenosis 70%–99%
All interventions: BMC-IRR	0.193 (0.128–0.285)	0.193 (0.127–0.288)
Angioplasty	0.125 (0.048–0.301)	0.125 (0.048–0.301)
BMS	0.194 (0.085–0.409)	0.202 (0.089–0.424)
WS	0.241 (0.140–0.395)	0.241 (0.137–0.404)

[a] Data are presented as mean probability (95% CI).

Table 7: Probability of stroke within 1 year in the territory based on location and intervention type for 50%–99% stenosis[a]

	Nonperforator Vessels (ICA/VA)	Perforator Vessels (BA/MCA)
Angioplasty	0.091 (0.013–0.492)	0.144 (0.049–0.386)
BMS	0.134 (0.034–0.448)	0.333 (0.122–0.718)
WS	0.226 (0.079–0.551)	0.246 (0.130–0.434)

[a] Data are presented as mean probability (95% CI).

Table 8: Lesion distribution

Intervention	Lesion Location	Count	Proportion (%)
Angioplasty ($n = 37$)	MCA	23	62.2
	ICA	7	18.9
	BA	3	8.1
	VA	4	10.8
BMS ($n = 29$)	MCA	0	0.0
	ICA	9	31.0
	BA	9	31.0
	VA	11	37.9
WS ($n = 49$)	MCA	24	50.0
	ICA	10	20.8
	BA	10	20.8
	VA	4	8.3

Table 9: Comparison of lesion distribution: BMC-IRR versus WASID

Lesion Location	BMC-IRR	WASID
MCA	41.2	32.5
ICA	22.8	21.6
BA	19.3	19.4
VA	16.7	20.3

year, while the BMS fell in between at 19.4% at 1 year. Angioplasty held its advantage over either stent in all vessels studied.

The estimated stroke probability in the angioplasty arm is lower than the estimated risk of stroke in WASID, and if these results were confirmed by another operator, it would show that angioplasty is a good adjunct to medical therapy in stroke prevention in the specific subgroup of patients that we studied here (symptomatic subjects with ≥70% arterial stenosis).

Our estimated stroke risk following intervention by using the BMS is 19.1% and is very close to the estimation reported by SSYLVIA (which also included the BMS), and this similarity adds validity to our findings. This is very close to the estimated stroke rate in WASID at 1 year (18%) and makes it hard to justify the BMS as an acceptable measure of stroke prevention in these patients. The WS with its 24.1% estimated risk of stroke at the end of the first year does not represent an acceptable alternative either.

The difference in the probability of stroke among the 3 arms is intriguing to us, especially the difference between the angioplasty and WS arms. This could be due to the fact that in angioplasty, there is no metal (stent) left behind with the possibility of a poor apposition to the vascular wall, or it could be because extra pressure is exerted on the arterial wall when deploying or delivering a stent. Another possible explanation is that there were more BAs in the WS arm than in the angioplasty arm, but this cause is less likely because only 2 of the 12 complications in the WS arm occurred in the BA, and these could not explain the different stroke rates.

We realize that this study has certain limitations. It is a not a randomized study between medical treatment and intervention; hence, the comparison between our results and the WASID results is limited at best, and a direct comparison be-

tween the 2 arms may show completely different results. The ongoing SAMMPRIS study is well-suited to answer this question as far as the WS is concerned because it compares the WS with BMT. However, it, unfortunately, does not compare the BMS or angioplasty with BMT; therefore, it does not examine their relative merits in stroke prevention. In our registry, the BMS arm did not have a lesion-location distribution comparable with the WS or angioplasty arms, but it had fewer perforator vessels which, if anything, should make the BMS arm appear to be safer. However, we found that the BMS arm did not prove to be safer; this finding suggests that angioplasty is, actually, safer than the BMS. Even so, we cannot assume that this comparison is valid due to the difference in lesion-location distribution. On the other hand, the distribution of vessels between the WS and angioplasty was similar, and we believe that the comparison between these 2 arms is more valid.

Another limitation of our study is the absence of randomization of the 3 different intervention arms (angioplasty, BMS, and WS), but the 3 arms had similar patient populations with similar clinical presentations, degree of vascular stenosis, and lesion distribution. Furthermore, the 3 devices were deployed by the same operating team, using the same technique and antiplatelet regimen; this feature makes the direct comparison between the 3 arms valid.

Conclusions

It appears that angioplasty compares favorably with the WASID study for stroke prevention in symptomatic subjects with ≥70% arterial stenosis, but neither stent-placement arm can make that claim. We believe that the relative safety of angioplasty in comparison with the WS is real and deserves a closer look and a larger study. This conclusion will need confirmation with a larger randomized study comparing BMT alone with BMT plus angioplasty and with BMT plus stent placement.

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