Robot-assisted carotid artery stenting: outcomes, safety, and operational learning curve

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OBJECTIVE Over the past 2 decades, robots have been increasingly used in surgeries to help overcome human limitations and perform precise and accurate tasks. Endovascular robots were pioneered in interventional cardiology, however, the CorPath GRX was recently approved by the FDA for peripheral vascular and extracranial interventions. The authors aimed to evaluate the operational learning curve for robot-assisted carotid artery stenting over a period of 19 months at a single institution.

METHODS A retrospective analysis of a prospectively maintained database was conducted, and 14 consecutive patients who underwent robot-assisted carotid artery stenting from December 2019 to June 2021 were identified. The metrics for proficiency were the total fluoroscopy and procedure times, contrast volume used, and radiation dose. To evaluate operator progress, the patients were divided into 3 groups of 5, 4, and 5 patients based on the study period.

RESULTS A total of 14 patients were included. All patients received balloon angioplasty and stent placement. The median degree of stenosis was 95%. Ten patients (71%) were treated via the transradial approach and 4 patients (29%) via the transfemoral approach, with no procedural complications. The median contrast volume used was 80 mL, and the median radiation dose was 38,978.5 mGy/cm². The overall median fluoroscopy and procedure times were 24.6 minutes and 70.5 minutes, respectively. Subgroup analysis showed a significant decrease in these times, from 32 minutes and 86 minutes, respectively, in group 1 to 21.9 minutes and 62 minutes, respectively, in group 3 ($p = 0.002$ and $p = 0.008$, respectively).

CONCLUSIONS Robot-assisted carotid artery stenting was found to be safe and effective, and the learning curve for robotic procedures was overcome within a short period of time at a high-volume cerebrovascular center.

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KEYWORDS angioplasty; carotid stenosis; Corindus; endovascular; robot; robot-assisted; stent

TECHNOLOGY in surgery is intended to optimize patient outcomes while minimizing complications and adverse events. Specifically, advancement in robotic engineering may aid operators in repetitive, challenging tasks with pinpoint precision and accuracy,¹ thereby overcoming the limits of physical ability and inherent human error, as well as limiting occupational hazards such as radiation exposure and infectious disease.^{1,2} Additionally, a great merit of robotic surgeries is the ability to perform them at remote locations, which would essentially provide lifesaving procedures to patients who are unable to present to a cerebrovascular center in a timely fashion.^{2–6} Historically, robots were largely designed for other surgical

specialties, mainly interventional cardiology;¹ it was more recently that they were engineered to assist in neurosurgical procedures such as depth electrode implantation for epilepsy, and minimally invasive spine surgeries.^{7,8}

The CorPath GRX (Corindus Inc.) robot-assisted platform is the latest robotic system initially designed for interventional cardiology procedures. However, based on the results of prior clinical studies on its predecessor, the CorPath 200 (Corindus Inc.),^{9,10} the robotic platform was approved by the US FDA and received a CE mark for percutaneous coronary (2016) and peripheral vascular (2018) interventions.¹ Following approval, a few studies have reported on the early experience with the CorPath GRX with

ABBREVIATIONS mRS = modified Rankin Scale; TIA = transient ischemic attack.
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FIG. 1. **Upper:** Robotic arm that holds the disposable cassette. **Lower:** Disposable cassette (1 use per procedure). 1 = sheath attachment; 2 = guide catheter rotation module; 3 = microadjustment buttons; 4 = robotic arm toggle button; 5 = guidewire rotation module; 6 = cassette lock; 7 = robotic arm feedback console.

neuroendovascular procedures such as diagnostic cerebral angiograms, carotid artery stenting, and a stent-assisted coil embolization of a basilar artery aneurysm.^{2,4,11,12} The latter was performed in Canada, as the CorPath robot is not yet approved for intracranial procedures in the US. In the present study, we looked at the outcome, safety, and learning curve for robot-assisted carotid artery stenting over a period of 19 months.

Methods

Study Population

In this retrospective study, the data of 14 patients, who were treated from December 2019 to June 2021, were collected from a single tertiary care, high-volume cerebrovascular center in the US. All patients treated with

robot-assisted carotid artery stenting were included. The CorPath GRX robot-assisted platform was used for the procedures (Figs. 1 and 2). Three surgeons were involved with the procedures, as follows. The first surgeon had 11 cases; the second, 2 cases; and the third, 1 case. The study protocol was reviewed and approved by the IRB. Patient consent was not obtained due to the retrospective nature of the study. The following data were collected from each patient's electronic medical record, from a prospectively maintained database: age, sex, history of hypertension, history of diabetes mellitus, history of coronary artery disease, history of hyperlipidemia, presentation (stroke, transient ischemic attack [TIA], or asymptomatic), smoking status, baseline modified Rankin Scale (mRS) score, medication information (antiplatelet, anticoagulation, and

FIG. 2. Upper: Remote physician unit. 1 = device joystick; 2 = guidewire joystick; 3 = catheter joystick; 4 = joystick feedback monitor; 5 = high-definition screen. **Lower:** Physician maneuvering the joysticks during a procedure.

TABLE 1. Demographics and baseline characteristics

Pt No.	Variable									
	Age (yrs)	F Sex	DM	HTN	CAD	TIA	Stroke	Asymptomatic	Baseline mRS Score 0 or 1	Current Smoker
1	75	No	Yes	No	No	No	Yes	No	Yes	No
2	77	No	No	No	No	Yes	No	Yes	Yes	No
3	74	No	No	Yes	No	No	Yes	No	Yes	No
4	60	No	No	Yes	No	No	Yes	No	Yes	Yes
5	72	No	Yes	Yes	Yes	Yes	No	No	Yes	No
6	62	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes
7	78	No	No	Yes	No	No	No	Yes	Yes	No
8	65	No	No	Yes	Yes	No	Yes	No	Yes	Yes
9	51	No	Yes	Yes	Yes	Yes	No	No	Yes	No
10	84	Yes	No	Yes	Yes	No	No	No	Yes	No
11	71	No	No	Yes	Yes	No	Yes	No	Yes	Yes
12	55	No	No	No	No	No	Yes	No	Yes	Yes
13	73	Yes	No	Yes	No	No	No	Yes	Yes	No
14	77	No	Yes	Yes	No	No	Yes	No	Yes	No
Total no. (%)	72.5*	3 (21.4)	4 (28.6)	11 (78.6)	6 (42.9)	3 (21.4)	8 (57.1)	3 (21.4)	14 (100)	5 (35.7)

CAD = coronary artery disease; DM = diabetes mellitus; HTN = hypertension; pt = patient.

* Presented as the mean age.

statin), procedural data, complication data, hospital length of stay, and follow-up data for functional outcomes. To preserve patient anonymity, and in compliance with IRB regulations, we do not present the full data for individual cases and instead report the aggregated data or individual deidentified data points.

Statistical Analysis

All statistical analyses were performed using Stata version 17.0 (StataCorp LLC) software. Descriptive statistics were summarized using median and IQR for continuous variables and proportions for categorical variables. To analyze procedural performance measures cumulatively, the procedures were sorted by the order in which they were performed over the study period. They were then divided into 3 groups of 5, 4, and 5 patients, from the earliest to the last procedure performed. Tests for performance measure trends, including total contrast volume used (milliliters), fluoroscopy time (minutes), total procedure time (minutes), and radiation dose (mGy/cm²), were performed across groups using the Jonckheere-Terpstra test. Due to the small sample size of the study, exact p values were calculated from Monte Carlo permutation tests of 100,000 random permutations. Missing data were not imputed. All tests were two-tailed, and a p value of < 0.05 was considered statistically significant.

Results

Demographics and Baseline Characteristics

Overall, 14 patients were treated with a robot-assisted carotid stent procedure at our institution, and the decision to use the robot was at the discretion of the surgeon. Three patients (21%) were female and 11 (79%) were male. The mean age of the cohort was 72.5 years (range 60–84

years). The most common comorbidities were hypertension (79%), coronary artery disease (43%), and diabetes mellitus (29%). Additionally, 8 patients (57%) presented with acute ischemic stroke, 3 patients (21%) presented with a TIA, and 3 patients (21%) were asymptomatic. Moreover, 5 patients (36%) were current smokers, and 3 patients (21%) were former smokers. Five patients (36%) were on a regimen of dual antiplatelet therapy (4 were receiving aspirin and clopidogrel, and 1 was receiving aspirin and ticagrelor) while 7 patients (50%) were on a single antiplatelet regimen (6 were receiving aspirin and 1 was receiving clopidogrel). All patients (100%) had an mRS score of 0 or 1 at baseline. Patient characteristics are summarized in Table 1.

Procedural Details and Robotic Parameters

Of the 14 patients, 10 (71%) were treated via the trans-radial approach and 4 (29%) via the transfemoral. All patients (100%) received a Precise Pro stent (Cordis, Cardinal Health) and underwent angioplasty with the Aviator (3 patients) or Aviator Plus (11 patients) balloon. Moreover, the median degree of stenosis (based on the North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) was 95% (IQR 80%–95%), and the median stenosis diameter was 1.45 mm (IQR 0.8–1.8 mm) (Table 2).

We used 4 objective metrics to determine the proficiency of robot-assisted carotid artery stenting: contrast volume, fluoroscopy time, procedure time, and radiation dose. The median contrast volume used was 80 mL (IQR 75–120 mL). The median fluoroscopy time was 24.6 minutes (IQR 22.9–33.2 minutes), and the median procedure time was 70.5 minutes (IQR 62–82 minutes). Finally, the median radiation dose was 38,978.5 mGy/cm² (IQR 29,872–56,758 mGy/cm²) (Table 3).

TABLE 2. Procedural details of patients who underwent robot-assisted carotid artery stenting

Pt No.	Variable					
	Degree of Stenosis (%)	Stenosis Diameter (mm)	Stent Type	Pre-stent Angioplasty	Balloon Type	Transradial Approach
1	95	1.8	Precise Pro	Yes	Aviator Plus	Yes
2	51	3.04	Precise Pro	Yes	Aviator	Yes
3	95	1.4	Precise Pro	Yes	Aviator Plus	Yes
4	95	1.6	Precise Pro	Yes	Aviator Plus	Yes
5	80	1.5	Precise Pro	Yes	Aviator Plus	No
6	95	0.8	Precise Pro	Yes	Aviator Plus	Yes
7	80	1.7	Precise Pro	Yes	Aviator Plus	Yes
8	95	1.8	Precise Pro	Yes	Aviator	No
9	99	0.6	Precise Pro	Yes	Aviator Plus	Yes
10	80	1	Precise Pro	Yes	Aviator	No
11	95	1	Precise Pro	Yes	Aviator Plus	Yes
12	99	0.5	Precise Pro	Yes	Aviator Plus	Yes
13	99	0.6	Precise Pro	Yes	Aviator Plus	No
14	70	2.5	Precise Pro	Yes	Aviator Plus	Yes
Overall	95 (80–95)*	1.45 (0.8–1.8)*		14 (100)†		10 (71.4)†

Pt = patient.

* Presented as the median (IQR).

† Presented as number of “yes” responses (%).

In addition, we divided the 14 patients into 3 groups of 5, 4, and 5 patients (based on the procedure date) and looked at the temporal trend of these parameters with time. The mean duration for fluoroscopy and procedure time decreased from 32 minutes and 86 minutes, respectively, in group 1 to 21.9 minutes and 62 minutes, respectively, in group 3, and the differences were statistically significant ($p = 0.002$ and $p = 0.008$, respectively). Similarly, the total contrast volume and radiation dose decreased from group

1 to group 3; however, the trend did not reach statistical significance ($p = 0.75$ and $p = 0.13$, respectively) (Table 4 and Fig. 3A–D).

Outcomes and Complications

All procedures were conducted successfully, with no procedural complications. The median hospital length of stay was 4.5 days (IQR 3–8 days) and the median follow-up duration was 90 days (IQR 45–90 days). Nine patients

TABLE 3. Robot-assisted procedure parameters

Pt No.	Variable			
	Contrast Vol (mL)	Fluoroscopy Time (mins)	Procedure Time (mins)	Radiation Dose (mGy/cm ²)
1	50	33.2	93	56,758
2	75	34.9	92	29,872
3	120	25.7	67	40,142
4	100	24.6	72	73,765
5	90	41.4	106	98,687
6	150	22.9	82	25,078
7	140	34.8	77	34,657
8	80	25.2	75	66,193
9	75	23.7	61	37,815
10	120	23.3	67	33,571
11	75	24.6	69	28,261
12	75	19.3	53	48,845
13	80	19.7	62	28,893
14	75	22.8	59	41,718
Median total (IQR)	80 (75–120)	24.6 (22.9–33.2)	70.5 (62–82)	38,978.5 (29,872–56,758)

Pt = patient.

TABLE 4. Trend for total contrast volume, fluoroscopy time, procedure time, and radiation dose across group 1 (patients 1–5), group 2 (patients 6–9), and group 3 (patients 10–14)

Group	Variable			
	Contrast Vol (mL)	Fluoroscopy Time (mins)	Procedural Time (mins)	Radiation Dose (mGy/cm ²)
1, mean	87	32	86	59,845
2, mean	111.25	26.7	73.8	40,963
3, mean	85	21.9	62	36,258
p value	0.7451	0.002	0.008	0.133

Boldface type indicates statistical significance.

FIG. 3. Bar graphs showing the trends for total contrast volume (A), fluoroscopy time (B), total procedure time (C), and radiation dose (D) across procedures.

TABLE 5. Outcomes of patients who underwent robot-assisted carotid artery stenting

Pt No.	Variable						
	Procedure Failure	Complications	LOS (days)	Mortality	mRS Score 0–2 at 90-Day FU	mRS Score 0–2 at Final FU	FU Duration (days)
1	No	No	11	No	NA	NA	NA
2	No	No	1	No	Yes	Yes	210
3	No	No	12	No	NA	NA	NA
4	No	No	19	No	Yes	Yes	90
5	No	No	3	No	Yes	Yes	335
6	No	No	5	No	NA	NA	NA
7	No	No	3	No	Yes	Yes	90
8	No	No	5	No	NA	NA	NA
9	No	No	5	No	Yes	Yes	90
10	No	No	1	No	Yes	Yes	60
11	No	No	4	Yes	NA	No	4
12	No	No	4	No	Yes	Yes	90
13	No	No	1	No	Yes	Yes	45
14	No	No	8	No	Yes	Yes	45
Overall	0 (0)*	0 (0)*	4.5 (3–8)†	1 (7.1)*	9 (100)*	9 (90)*	90 (45–90)†

FU = follow-up; LOS = length of stay; NA = not applicable; pt = patient.

* Presented as number of “yes” responses (%).

† Presented as the median (IQR).

(64%) presented for the 90-day follow-up, and all 9 (100%) had a favorable mRS score of 0 to 2. At final follow-up, 90% of patients had a favorable mRS score. One patient (7%) died 4 days after the procedure. The patient's death was unrelated to the procedure and was due to the severity of the initial presentation (Table 5).

Discussion

Neuroendovascular surgery is a continuously evolving specialty that aims to make use of novel techniques, tools, and technology in order to improve patient care. With the advancement of robotic engineering in surgery, along with the advantages it presents and the implications of its use on the future of healthcare, it is important for neurointerventionalists and postgraduate fellows to adapt to this technology.

Our study results show that robot-assisted carotid artery stenting is safe and feasible. All patients had successful procedures, and there were no technical or access-site complications. In addition, the procedures were able to be performed using both the transradial and transfemoral approaches. In a series of 10 patients who underwent both robot-assisted diagnostic cerebral angiograms as well as robot-assisted carotid artery stenting, Sajja et al. reported successful procedures in all patients with no complications encountered.¹² Similarly, Nogueira et al. reported the feasibility of the CorPath GRX for carotid artery stenting in symptomatic disease.¹¹ Moreover, multiple retrospective studies have shown that the transradial approach is as feasible as the transfemoral approach, with the exception of very few cases requiring transfemoral conversion due to tortuous anatomy or bovine arch configuration.^{4,11,12} This is very important, as the transradial approach has gained widespread adoption by interven-

tionists, with evidence showing increased patient preference as well.^{13–15}

As with any new technology or technique, there is a learning curve to overcome. We conducted a learning curve analysis and chose objective metrics including contrast volume, procedure and fluoroscopy times, and radiation dose. Our results showed a statistically significant decrease in fluoroscopy time between the first 5 robot-assisted carotid artery stents (32 minutes) and the last 5 (21.9 minutes) ($p = 0.002$). A similar, statistically significant decrease in procedure time (from 86 minutes to 62 minutes) was noted as well ($p = 0.008$). These findings are supported by those of Weisz et al., which showed that only 3 robot-assisted cases were needed to achieve significant reductions in both procedure and fluoroscopy times ($p = 0.008$ and $p = 0.003$, respectively).¹⁶ Similarly, Sajja et al. found that performance measures improved after 3 robot-assisted procedures, and Weinberg et al. reported improved procedure times with additional cases, without compromising patient safety.^{4,12} In addition, an early comparison of manual versus robot-assisted carotid artery stenting showed that the mean procedure time was significantly longer in the robotic procedures (85.0 minutes vs 61.2 minutes, $p = 0.0231$).⁴ However, with additional robot-assisted cases, our current average procedure matches that of traditional manual cases.

Although not statistically significant, our study results also show a trend toward reduced radiation dose and contrast volume, signifying quicker procedures and further indicating a favorable learning curve that can be overcome with continued use. Our findings are in line with a study on the use of robotics for interventional cardiac procedures that reported operator prowess after 10 cases performed with the CorPath GRX.¹⁷ Our findings, and those in the

literature, indicate a relatively short learning curve for robotic procedures compared with other new interventions. For example, performing 64 to 95 transradial cases are required for transfemoral interventionalists to overcome the learning curve for endovascular neurosurgery, and 39 to 50 cases for interventional cardiologists.^{16,18} Hence, this favorable learning curve for robot-assisted neurointerventions could encourage interventionalists to adopt this technology in their practice.

In addition to increased precision and accuracy, adopting robotic technology may reduce radiation exposure to the healthcare team by as much as 97%, thereby decreasing the risk of malignancies, including left-sided brain tumors, breast cancer, and melanomas, the incidence of which usually increases with cumulative ionizing radiation.^{9,19,20} Most importantly, robotic technology has the potential for executing procedures from remote locations. The CorPath GRX was successful in performing percutaneous coronary interventions from 20 and 100 miles away.^{5,6} Therefore, with specific neuroendovascular engineering and software modifications,²¹ a short learning curve, and eventual FDA approval for intracranial procedures, robotic systems bear a great potential to provide life-saving procedures, including mechanical thrombectomies and ruptured aneurysm embolizations, to patients in rural areas who are without immediate access to cerebrovascular centers.

Depending on regional or institutional variability, the average cost of the CorPath GRX robot system is \$500,000.²² Furthermore, the disposable cassette costs an additional \$559 for each procedure. This may deter some hospitals and interventionalists, especially small hospital systems in rural areas, from adopting this technology. However, patient safety and the lower cumulative radiation exposure of physicians must be taken into consideration. Also, as technology is continuously improving, there is potential to establish neuroendovascular networks capable of performing emergency procedures remotely. Therefore, the seemingly expensive cost may be justified, as it may not only save more lives but also reduce costs long-term, given the healthcare expenditures associated with stroke morbidity.²³

Due to the numerous advantages that the CorPath GRX robot system provides, it is important that its use is incorporated as a component of neuroendovascular fellowship training whenever possible. This can include formal, proprietary in-service training as well as continuous supervision by faculty to ensure that operator proficiency is achieved.

Limitations

This study is limited by its retrospective design, lack of randomization, lack of long-term patient follow-up, lack of objective criteria in choosing the robotic technique, and small sample size. Also, the data are from a single center in the US and, therefore, the generalizability of the results is limited. However, learning curve analysis was done with objective metrics. Our findings show that the learning curve for robot-assisted neuroendovascular procedures can be overcome. However, future prospective clinical trials are needed to further elucidate their safety,

efficacy, and consistency, and to determine the subsequent direction.

Conclusions

Our study results show that robot-assisted carotid artery stenting is safe and efficacious, and that the learning curve can be overcome with relatively few cases at a high-volume cerebrovascular center. However, the full potential of robotics in neuroendovascular surgery has yet to be achieved and future clinical studies are needed to consolidate its role in the future of neurological surgery.

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Disclosures

Dr. Jabbour is a consultant for Medtronic and MicroVention. Dr. Tjoumakaris and Dr. Gooch are consultants for Stryker. Dr. Tjoumakaris is a consultant for Medtronic and MicroVention.

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Conception and design: Jabbour, Abbas, Al Saiegh. Acquisition of data: Abbas, Al Saiegh, El Naamani, Sioutas, Weinberg. Analysis and interpretation of data: Jabbour, Abbas, Chen. Drafting the article: Abbas. Critically revising the article: Jabbour, Abbas, Al Saiegh, El Naamani, Tjoumakaris, Gooch, Herial, Rosenwasser. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Jabbour. Statistical analysis: Chen, Velagapudi. Study supervision: Jabbour.

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