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Placing the balloon-guide catheter in the high cervical segment of the internal carotid artery is associated with improved recanalization

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ABSTRACT

Background Mechanical thrombectomy (MT) is part of the standard of care for stroke treatment, and improving its efficacy is one of the main objectives of clinical investigation. Of importance is placement of the distal end of balloon-guided catheters (BGC). We aim to determine if this influences outcomes.

Methods We analyzed data from the ASSIST Registry, an international, multicenter prospective study of 1492 patients. We divided patients treated with BGC according to the placement of the BGC: low cervical (LCG (the lower 2/3 of cervical internal carotid artery (ICA)) or high cervical (HCG (upper 1/3 of cervical ICA, petro-lacerum or higher)). We analyzed characteristics and outcomes overall and stratified on the primary MT technique: Stent-Retriever only (SR Classic), Combined use of aspiration catheter and SR (Combined), and Direct Aspiration (ADAPT).

Results Our study included 704 subjects —323 in the low cervical and 381 in the high cervical groups. Statistical differences were seen in the proportion of females and tandem lesions (both higher for LCG). Placing the BGC in the high cervical segment is associated with better recanalization rates (expanded treatment in cerebral infarction (eTICI) score of 2c-3) at the end of the procedure (P<0.0001) and shorter procedures (P=0.0005). After stratifying on the three primary techniques (SR Classic, Combined, and ADAPT), placing the BGC in the high segment is associated with a better first-pass effect (FPE), less distal emboli, and better clinical outcomes in the SR Classic technique.

Conclusions Placing the distal end of the BGC at the high cervical segment or higher is associated with better recanalization.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ BGC improves recanalization and decreases distal emboli when performing a mechanical thrombectomy procedure.

WHAT THIS STUDY ADDS

⇒ Recanalization rates were associated with improvement when placing the distal end of the BGC in the high cervical segment. The SR Classic technique was associated with enhanced FPE and clinical outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ When using a BGC, placing the distal end as high as possible may improve recanalization rates and seems to be mandatory when performing the SR Classic technique.

INTRODUCTION

Mechanical thrombectomy (MT) is part of the standard of care in stroke treatment,[1] and is increasingly being adopted every year, regardless of the time of onset[2 3] or the size of the ischemic core.[4–7] The first trials and studies aimed to obtain recanalization after several passes. Currently, studies are trying to determine the best technique to improve the first-pass effect and achieve complete recanalization.[8]

Three main MT techniques are now considered standard of care: Stent Retriever (SR) alone (SR Classic), A Direct Aspiration First Pass Technique (ADAPT), and a combination of both (SR Combo); these techniques have been compared in some studies.[9]

Using balloon-guide catheters (BGC) has been associated with improved recanalization, fewer distal emboli, and lower complications.[10–13] While some studies have proved the effectiveness of an intermediate catheter,[13] others have seen that the efficacy of MT improves with the size of the intermediate catheter.[14] The location of the distal access catheter has also been associated with better recanalization rates in ADAPT procedures,[15] and procedures with BGC.[16 17] However, none of the studies has been able to correlate these findings with better clinical outcomes. The location of the distal end of the BGC can be modified before proceeding with the pass; therefore, understanding its association with the recanalization rate can improve the results of the pass. Placing the BGC lower may increase the probability that the internal carotid artery (ICA) may collapse during the reversing of the flow, making use of BGC ineffective.[18] We analyzed data from the ASSIST Registry to study the relationship

Table 1 Comparison of baseline and procedural characteristics for patients with BGC placed in high cervical/petro-lacerum or higher vs low cervical

	LCG (n=323)	HCG (n=381)	P-value
Demographics/medical history			
Age (years), mean (SD)	71.7 (13.3)	70.6 (14.4)	0.36
Female, n (%)	180 (55.7)	183 (48.0)	0.008
Hypertension, n (%)	220 (69.6)	250 (66.1)	0.32
Atrial fibrillation, n (%)	112 (35.2)	129 (34.3)	0.86
Previous ischemic stroke, n (%)	40 (12.7)	56 (15.0)	0.44
Previous transient ischemic stroke, n (%)	12 (4.0)	18 (4.9)	0.63
Diabetes, n (%)	67 (21.1)	74 (19.6)	0.52
Extracranial carotid artery disease, n (%)	26 (8.5)	24 (6.5)	0.43
Dyslipidemia, n (%)	135 (44.1)	170 (45.7)	0.76
Stroke characteristics			
Mode of presentation, n (%)			0.03
Wake-up stroke	55 (17.5)	91 (24.3)	
Witnessed stroke	162 (51.6)	202 (53.9)	
Unwitnessed stroke	97 (30.9)	82 (21.9)	
NIHSS score, mean (SD)	13.7 (6.6)	14.7 (6.6)	0.27
Baseline CT ASPECTS*, mean (SD)	7.7 (1.5)	7.8 (1.3)	0.64
Pre-stroke mRS 0–2, n (%)	275 (87.0)	341 (90.7)	0.23
Clot location*, n (%)			0.04
ICA	88 (27.2)	70 (18.4)	
M1	156 (48.3)	202 (53.0)	
M2	76 (23.5)	101 (26.5)	
Distal (A1, A2, M3)	3 (0.9)	8 (2.1)	
Extracranial tandem lesions present, n (%)	63 (19.5)	46 (12.1)	<0.0001
Procedural characteristics			
Primary technique, n (%)			0.28
SR Classic	92 (28.5)	155 (40.7)	
SR Combination	188 (58.2)	163 (42.8)	
ADAPT	43 (13.3)	63 (16.5)	
IV tPA, n (%)	141 (43.7)	129 (33.9)	0.03
General anesthesia, n (%)	71 (22.0)	149 (39.1)	0.13
Time last known well to end of procedure, n (%)			0.88
<6 hours	172 (56.8)	210 (58.8)	
6–24 hours	119 (39.3)	133 (37.3)	
>24 hours	12 (4.0)	14 (3.9)	
Procedure time (minutes), mean (SD)	45.3 (31.2)	35.8 (23.6)	0.0005
Balloon inflated, n (%)	286 (88.5)	355 (93.2)	0.14
Balloon-guided aspiration used, n (%)	253 (78.3)	323 (84.8)	0.28
Pump used, n (%)[1]	47 (18.6)	43 (13.3)	0.27

*These variables are core lab reported. All other variables are site-reported.([1]) Limited to patients where BGC aspiration was used.
ADAPT, a direct aspiration first pass technique; ASPECTS, Alberta Stroke Program Early CT Score; HCG, high cervical group; ICA, internal carotid artery ; IV tPA, intravenous tissue plasminogen activator; LCG, low cervical group; mRS, modified Rankin Score; NIHSS, National Institute of Health Stroke Scale; SD, standard deviation; SR, stent retriever.

Table 2 Comparison of outcomes overall for patients with BGC placed in high cervical/petro-lacerum (HCG) or higher vs low cervical (LCG)

	LCG (n=323)	HCG (n=381)	P-value
eTICI 2 c or greater on first pass for TTO*, n (%)	122 (39.4)	175 (48.2)	0.05
Bailout, n (%)[1]	54 (16.8)	62 (16.4)	0.93
Number of passes for treatment of target occlusion, n (%)			0.31
1–2	261 (80.8)	319 (83.7)	
≥3	62 (19.2)	62 (16.3)	
eTICI 2 c or greater at end of procedure*, n (%)	197 (61.0)	282 (74.8)	<0.0001
Symptomatic ICH up to 48 hours post-procedure, n (%)	5 (1.5)	10 (2.6)	0.34
NIHSS at 24 hours, mean (SD)	7.6 (7.0)	6.9 (7.1)	0.56
Embolization to new territory*, n (%)	1 (0.3)	4 (1.1)	0.22
Distal emboli*, n (%)	153 (47.5)	141 (37.4)	<0.0001
90-day mRS 0–2, n (%)	169 (55.4)	234 (62.7)	0.10

*These variables are core lab reported. All other variables are site-reported.Bailout is defined as switching to another technique for treatment of target occlusion (TTO), or to a procedure other than TTO to improve eTICI. These techniques include treatment of additional clot, distal emboli, embolization to new territory, or stenosis.
BGC, balloon guide catheter; eTICI, expanded treatment in cerebral infarction; HCG, high cervical group; ICH, intracranial hemorrhage; LCG, low cervical group; mRS, modified Rankin Score; NIHSS, National Institute of Health Stroke Scale; TTO, treatment of target occlusion.

between the location of the BGC, recanalization rates and clinical outcomes.[2]

MATERIAL AND METHODS

The ASSIST registry was a prospective, global, multicenter registry of anterior circulation acute ischemic stroke patients with a large vessel occlusion (LVO) who underwent treatment with one of the interventional techniques using Stryker Neurovascular devices for the first pass. This Registry aimed to assess the procedural success and clinical outcomes associated with various techniques for mechanical thrombectomy in LVO in the anterior circulation.[19] It included data from 1492 patients enrolled in 71 North American, European, and Asian centers from January 2019 to May 2022. See primary publication for further details.[19] Inclusion and exclusion criteria can be found in the supplement.

We limited the analysis to patients where a BGC manufactured by Stryker (FlowGate[2] or Merci) was used for the first pass, and we divided them into two groups depending on the placement of the distal end of BGC on the first pass for the treatment of target occlusion. BGC placement in the high cervical (upper 1/3 of cervical ICA) or petro-lacerum or higher was included in the 'high cervical' group (HCG), and BGC placement in the lower 2/3 of cervical ICA was included in the 'low cervical' group (LCG). Determination of the BGC location was performed by the research team at each center.

Demographics, medical history, stroke characteristics including presentation, National Institute of Health Stroke Scale (NIHSS), along with procedural characteristics such as first pass technique, procedure time, and use of intravenous tissue plasminogen activator (IV tPA) and/or general anesthesia were site-reported. The independent imaging core

Table 3 Comparison of outcomes within primary technique for patients with BGC placed in high cervical/petro-lacerum or higher (HCG) vs low cervical (LCG)

	SR classic (n=247)			SR combination (n=351)			ADAPT (n=106)		
	LCG (n=92)	HCG (n=155)	P-value	LCG (n=188)	HCG (n=163)	P-value	LCG (n=43)	HCG (n=63)	P-value
eTICI 2c or greater on first pass for TTO*, n (%)	29 (32.2)	81 (56.6)	<0.0001	85 (47.2)	72 (44.7)	0.65	8 (20.0)	22 (37.3)	0.09
Bailout, n (%)[1]	13 (14.1)	15 (9.7)	0.34	17 (9.0)	18 (11.1)	0.48	24 (57.1)	29 (46.8)	0.37
Number of passes for treatment of target occlusion, n (%)			<0.0001			0.63			0.83
1–2	72 (78.3)	140 (90.3)		161 (85.6)	137 (84.0)		28 (65.1)	42 (66.7)	
≥3	20 (21.7)	15 (9.7)		27 (14.4)	26 (16.0)		15 (34.9)	21 (33.3)	
eTICI 2c or greater at end of procedure*, n (%)	52 (56.5)	119 (77.8)	0.0004[2]	119 (63.3)	111 (68.9)	0.20	26 (60.5)	52 (82.5)	0.01[2]
Symptomatic ICH up to 48 hours post-procedure, n (%)	2 (2.2)	3 (1.9)	0.88	3 (1.6)	4 (2.5)	0.39	0 (0.0)	3 (4.8)	0.27[3]
NIHSS at 24 hours, mean (SD)	8.6 (7.7)	6.0 (6.4)	0.005	7.0 (6.3)	7.9 (7.6)	0.34	8.1 (7.9)	6.1 (7.2)	0.35
Embolization to new territory*, n (%)	0 (0.0)	2 (1.3)	0.53([3])	1 (0.5)	2 (1.2)	0.42	0 (0.0)	0 (0.0)	N/A([4])
Distal emboli*), n (%)	42 (45.7)	47 (30.7)	<0.0001	88 (47.1)	71 (44.1)	0.58	23 (53.5)	23 (36.5)	0.08([2])
90-day mRS 0–2, n (%)	43 (48.9)	97 (65.1)	0.04	103 (57.2)	88 (54.3)	0.51	23 (62.2)	49 (79.0)	0.07([2])

1. *These variables are core lab reported. All other variables are site-reported.Bailout is defined as switching to another technique for treatment of target occlusion (TTO), or to a procedure other than TTO to improve eTICI. These techniques include treatment of additional clot, distal emboli, embolization to new territory, or stenosis.([2]) P-value adjusted for site could not be calculated, so unadjusted P-value presented. Interpret with caution, as unadjusted P-values are smaller (more significant) than adjusted P-values.([3]) P-values adjusted for site could not be calculated due to zero cell count. Unadjusted P-value using Fisher's Exact test are presented. Interpret with caution, as unadjusted P-values are smaller (more significant) than adjusted p-values.
2. P-value could not be calculated as there were no embolization to new territory in either low or high cervical groups.

BGC, balloon-guided catheter; eTICI, expanded treatment in cerebral infarction; HCG, high cervical group; ICH, intracranial hemorrhage; LCG, low cervical group; mRS, modified Rankin Score.; NHISS, National Institute of Health Stroke Scale.

lab assessed clot location, Alberta Stroke Program Early CT Score (ASPECTS), site of occlusion, and reperfusion.

The primary outcome for this secondary analysis was final recanalization (measured as final expanded treatment in cerebral infarction (eTICI) of 2c or greater, core lab reported), and secondary variables were first-pass effect (FPE, measured as expanded treatment in cerebral infarction (eTICI) 2c or better after the first pass, core lab reported), good clinical outcome (defined as modified Rankin Score (mRS) at 90 days of 0 to 2, site reported) and the presence of symptomatic intracranial hemorrhage within 48 hours of MT (site reported). Distal emboli (core lab reported), embolization to new territory (core lab reported), and dissection (core lab reported) were also analyzed.

Stryker Neurovascular ensured this study was conducted in compliance with generally accepted standards of Good Clinical Practice (GCP), 21 Code of Federal Regulations, (CFR) part 812 and all applicable regulatory requirements. The investigators also ensured the study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and that are consistent with GCP and applicable local regulatory requirements. Any adverse event associated with the use of Stryker Neurovascular products was reported in accordance with local regulatory requirements.

STATISTICAL METHODS

Means and frequencies are presented, as appropriate. Normality of continuous variables was assessed. Analyses are adjusted for clustering within the site. A Chi-squared test with random effects was used to adjust for clustering for categorical variables. A general linear model with mixed effects was used to adjust for clustering for continuous variables. On the few occasions where the Chi-squared algorithm would not converge, a Chi-square with no adjustment was used (and noted within the footnotes). Fisher's Exact test (unadjusted for site) was used when one group had a zero-cell count (noted within the table footnotes).

Two multivariable regression analyses were performed, with outcomes of first pass eTICI 2c or greater and final eTICI 2c or greater. Variables in the model were identified a priori by the investigator and forced into the model. No stepwise selection methods were used. Models were adjusted for clustering within site.

All analyses were performed using SAS 9.4 (Cary, NC). P-value <0.05 was considered significant.

RESULTS

Of the 1492 patients in the registry, 704 fulfilled the inclusion criteria and were included in the analysis: 381 in the HCG and 323 in the LCG.

Baseline and procedural characteristics are included in table 1. There were statistically significant differences in the percentage of females (higher in the LCG), the mode of presentation (more wake-up strokes in the HCG and more unwitnessed strokes in the LCG), the location of the clot (more ICA in the LCG) and the percentage of tandem lesions (19.5% for LCG and 12.1%

Table 4 Multivariable regression with final eTICI (≥2c) as outcome and First Pass Effect (eTICI 2c after first pass)

	Final eTICI (≥2c)		First pass efficacy (≥2c)	
	Or (95% CI)	P-value	Or (95% CI)	P-value
HCG	1.75 (1.21, 2.54)	0.004	1.42 (0.94, 2.14)	0.10
Primary technique		0.72([2])		0.01
SR Classic	Reference		Reference	
SR Combination	1.03 (0.70, 1.52)	0.88	1.09 (0.68, 1.73)	0.71
ADAPT	1.19 (0.77, 1.83)	0.43	0.48 (0.28, 0.83)	0.009
Clot location*		0.003([2])		0.18
ICA	Reference		Reference	
M1	1.27 (0.99, 1.62)	0.06	1.24 (0.92, 1.67)	0.16
M2	0.64 (0.47, 0.89)	0.008	1.08 (0.77, 1.50)	0.65
Other distal (A1, A2, M3)	0.32 (0.07, 1.42)	0.13	0.12 (0.01, 1.11)	0.06
Extracranial tandem lesions	1.76 (1.20, 2.56)	0.004	1.41 (0.86, 2.34)	0.17
General anesthesia	1.53 (1.08, 2.16)	0.02	1.29 (0.88, 1.90)	0.18
IV tPA	1.08 (0.83, 1.40)	0.56	0.97 (0.73, 1.29)	0.81

*These variables are core lab reported. All other variables are site-reported. All variables in the model were selected *a priori* by the investigator and forced into the model. No stepwise selection methods were used.
ADAPT, a direct aspiration first pass technique; HCG, high cervical group; IV tPA, intravenous tissue plasminogen activator; SR, stent retriever.

for HCG (P<0.0001)). Half (49.5%) of the patients with extracranial tandem lesions received an intracranial or extracranial stent during the procedure.

Regarding the procedure itself, there were no statistically significant differences in BGC placement between the primary technique (P=0.28), the time from last-seen well to the end of the procedure, and the use of general anesthesia. Higher use of IV-tPA was seen in the LCG (43.7% in the LCG and 33.9% in the HCG, P=0.03), and the procedure length was shorter for the HCG (23.6 minutes vs 31.2 minutes, P=0.0005). Femoral access was employed in all but 10 patients.

Regarding the outcomes in these two groups, table 2 shows statistically significant differences in the recanalization rate at the end of the procedure (eTICI 2c or greater) for the HCG (74.8% vs 61.0%, P<0.0001), and marginally significant differences in first pass eTICI 2c or greater for the HCG (48.2% vs 39.4%, P=0.05). There were fewer distal emboli in the HCG (37.4% vs 47.5, P<0.0001) but no significant differences in embolization to new territories (P=0.22). No significant differences were seen in the 90-day mRS 0–2, bailout techniques, number of passes, or symptomatic intracranial hemorrhage up to 48 hours post-procedure. No patients experienced dissection. Stratifying the sample based on the primary technique results in 247 patients in the SR Classic group, 351 in the SR Combination group, and 106 in the ADAPT group, as shown in table 3. The association between location of the distal end of the BGC and outcomes varied across each primary technique.

In the SR Classic group, placing the BGC in the HCG is associated with better eTICI 2c or greater on the first pass (56.6% vs 32.2% P<0.0001) and at the end of the procedure (77.8% vs 56.5, P=0.0004), a greater chance of removing the clot in 1 or 2 passes (90.3% vs 78.3%, P<0.0001), less chance of distal emboli (P<0.0001) and better clinical outcome measured with mRS at 90 days (65.1% vs 48.9%, P=0.04).

No significant differences were seen between outcomes and BGC placement in the SR Combination arm. Only eTICI 2c or greater at the end of the procedure was significantly different across low and high cervical groups for ADAPT.

We performed two multivariable regression analyses for the two reperfusion outcomes frequently presented in the literature: final eTICI and FPE (table 4). The HCG had significantly higher odds (1.75, 95% confidence interval (CI) (1.21, 2.54)) of achieving final eTICI≥2c (P=0.004) after adjusting for other variables in the model. While the HCG had higher odds of achieving first-pass efficacy (1.42, 95% CI (0.94, 2.14)), this did not reach statistical significance (P=0.10).

DISCUSSION

The analysis aimed to investigate the influence of the location placement of the BGC in the ICA during MT on recanalization rates. In the era of expanding selection criteria for MT, optimizing techniques for efficient recanalization is crucial. The analysis used data from the ASSIST registry, encompassing a substantial dataset of patients subjected to various MT techniques. Higher cervical placement of the tip of the BGC was associated with higher rates of recanalization at the end of the procedure and also better clinical outcomes when using the single SR technique.

The use of BGC has been unequivocally associated with better results for MT regardless of the chosen modality.[12 20–23] From the initial trials and registries, it is clear that the primary objective of MT procedures was final recanalization.[1] However, several publications have shown that the FPE is the key variable that is linked with better clinical results and is more cost-efficient.[8 24] Therefore, it is imperative to improve FPE to achieve optimal outcomes. Enhancing FPE can significantly reduce the likelihood of clot rupture and distal migration, both of which are closely linked to unfavorable outcomes.[25–27] Therefore, prioritizing the improvement of FPE can play a crucial role in ensuring better clinical outcomes for patients.

Placing the BGC in the high cervical segment was associated with higher rates of recanalization. This finding held after adjustment for technique, clot location, general anesthesia and other stroke and procedural characteristics in a regression model. On stratification by technique, this held within the SR Classic group and ADAPT arms, but not within the SR Combination arm. We found that placing the BGC in the high cervical segment was associated with a higher FPE, better clinical outcome, and less clot migration for SR Classic patients. Therefore, it is crucial when employing the SR Classic technique to carefully consider BGC placement, as, BGC placement in the high cervical may enhance recanalization and may result in good 90-day outcomes, while potentially decreasing distal clot migration. This is consistent with results already published in the literature.[25–27]

Consequently, these data suggest placing the BGC as far as safely possible into the high cervical when performing this technique may lead to better angiographic and clinical outcomes. In the combined and ADAPT groups, this association with improvement for first-pass efficacy was not seen, probably because the presence of an intermediate catheter inside the BGC makes it harder to obtain an effective flow reversal, and therefore, the BGC loses one of its main advantages in these two groups.[13] Unfortunately, the registry did not measure successful flow reversal.

The association with improved recanalization in the high cervical group aligns with previous studies associating BGCs

with enhanced outcomes in MT.[11 17 26] The analysis extends this understanding by emphasizing the importance of the BGC's distal end placement within the high cervical segment, showcasing a potential impact on FPE and final pass effect.

Demographic differences between the groups were noted, with more wake-up strokes and fewer distal ICA clots in the HCG. A shorter procedure time in the HCG was noted, potentially highlighting the efficiency gained from optimal BGC placement.

Despite the robust methodology of the ASSIST Registry, limitations exist as it is a non-randomized study, and some selection bias may have been present in the selection of the patients. However, data are representative of stroke patients all around the world. The size of sub-samples when stratified by technique vary, making interpretation difficult as the ADAPT group has less power than the SR Classic and SR Combination groups. Clinical outcomes were not blinded and the selection of BGC usage may be influenced by technique preference. Another limitation of this analysis was mandatory use of Stryker devices for the first pass. While it is possible that this may induce bias, the operator was not limited to Stryker devices on follow-up passes.

CONCLUSIONS

In conclusion, this study provides valuable insights to the relationship between the location of BGC placement and recanalization rates during MT, with better recanalization associated with higher placement. The results emphasize the potential benefits of placing the distal end of the BGC in the high cervical segment, offering a practical consideration for interventionalists seeking to optimize their MT techniques. Further prospective studies and randomized trials are warranted to validate these findings and explore potential refinements in endovascular stroke treatment strategies.

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Contributors MM drafted the initial manuscript and is responsible for the overall content as the guarantor. LLP analyzed the data. All authors were involved and made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of the data; revising it critically for important intellectual content; final approval of the version published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethics approval This study involves human participants and was performed in compliance with the World Medical Association's Declaration of Helsinki. This study was approved by Advocate Health and Hospitals 'Western Institutional Review Board Puyallup, WA' 20191803; Buffalo University 'Western Institutional Review Board Puyallup, WA' 20191803; Kaiser Permanente – LA 'Kaiser Permanente Southern California Institutional Review Board Pasadena, CA' 12330; Medical University of South Carolina 'Institutional Review Board for Human Research (IRB) Office of Research Integrity (ORI) Medical University of South Carolina Palmetto Place Office Park Charleston, SC' Pro00089838 Thomas Jefferson University 'Western Institutional Review Board Puyallup, WA' 20191803; U Mass 'Western Institutional Review Board Puyallup, WA' H00020421_2; West Virginia University Hospital 'West Virginia University Office of Humas Research Protections Morgantown, WV' 1908690661; Semmes Murphey Foundation 'University of Tennessee Health Science Center IRB Memphis, TN' 20-07240- XP; Riverside Methodist – OHRI 'Western Institutional Review Board Puyallup, WA' Institution Tracking: 1555244; IRB Tracking: 20191803; UC Irvine 'Western Institutional Review Board Puyallup, WA' Institution Tracking: HS# 2020-5978; IRB Tracking: 20191803;UCLA 'UCLA Office of the Human Protection Research Protection Program Los Angeles, CA' 20-000041-CR-00002;Research Institute, University of Kansas Medical Center 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1427195-1; IRB Tracking: 20191803; Valley Baptist Medical Center- Harlingen 'MetroWest Medical Center IRB Framingham, MA' 2021-012 WellStar Health System/ Kennestone Hospital 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1427195-1; IRB Tracking: 20191803; St Mary's Medical Center 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1547720-1; IRB Tracking: 20191803; Geisinger Medical Center 'Geisinger IRB Danville, PA' 2019-0877; Los Robles Hospital 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1203360-1;IRB Tracking: 20191803; Baptist Jacksonville 'Baptist Health IRB Jacksonville, FL' 19-78;Mount Sinai 'Mount Sinai School of Medicine IRB New York, NY' HS#: STUDY-19-00986-CR002University of S. Florida/Tampa General 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1331689-1; IRB Tracking: 20191803; Westchester Medical Center 'New York School of Medicine, Office of Research Administration Valhalla, NY' 14316; Stanford 'Stanford University ResearchCompliance Office Palo Alto, CA' 60155; Banner Desert (Teleb) 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1247829-1; IRB Tracking: 20191803; Memorial Regional Healthcare System 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1427195-1; IRB Tracking: 20191803; Mercy St Vincent 'Research Oversight and Education Mercy Health St. Vincent Medical Center Toledo, OH' IRB 2019-59; University of Oklahoma Medical Center 'University of Oklahoma Health Science Center IRB Oklahoma City, OK' 704594 McLaren Regional Medical Center 'Mclaren Research Integrity IRB Auburn Hills, MI' 2019-00061; Legacy Emanuel Medical Center 'Legacy Research Institute Portland, OR' No approval number; approval date 8-29-19; Dignity Health - Mercy San JuanDignity Health CA/NV IRB Cordova, CA 1738412-2; Rhode Island Hospital Lifespan Research Protection Office of Research Administration Providence, RI 1525230-19; Aurora St Luke's 'Western Institutional Review Board Puyallup, WA' Work Order Number: 1-1427195-1; IRB Tracking: 20191803; University Medical Center - El Paso Texas Tech University Health Sciences Center El Paso IRB El Paso, TX' 074445; KaiserPermanente Fontana Medical Center 'Kaiser Permanente Southern California Institutional Review Board Pasadena, CA' 12328; Indiana University 'IndianaUniversity Institutional Review Board Indianapolis, IN' 2003685877; Doctors MedicalCenter Modesto 'MetroWest Medical Center Framingham, MA'

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