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Geographic variability and operator trends of transcatheter edge-to-edge repair in the United States

Joseph Heaton MD¹ | Steven Imburgio MD¹ | Sowmya Dandu MD¹ | Anmol Johal MD¹ | Ndausung Udongwo MD¹ | Anton Mararenko DO¹ | Arif Asif MD¹ | Jesus Almendral MD² | Brett Sealove MD² | Jeffrey Selan MD² | Daniel Kiss MD² | Matthew Saybolt MD²

¹Department of Medicine, Jersey Shore University Medical Center, Neptune City, New Jersey, USA

²Department of Medicine, Division of Cardiology, Jersey Shore University Medical Center, Neptune City, New Jersey, USA

Correspondence

Steven Imburgio, MD, Department of Medicine, Jersey Shore University Medical Center, Neptune, NJ 07753, USA. Email: steven.imburgio@hmhn.org

Abstract

Backgrounds: Transcatheter edge-to-edge repair (TEER) devices are used for primary mitral regurgitation (MR) and secondary MR. Despite the growing use of TEER devices, there have not been many studies on operator experience or procedure volumes by state.

Aims: We aimed to investigate nationwide operator volume trends and geographic variation in access to TEER.

Methods: The United States Center for Medicare and Medicaid Services (CMS) National Medicare Provider Utilization and Payment Database (MPUPD) was analyzed between 2015 and 2020 for initial TEER procedures.

Results: Procedure volume and total operators increased yearly from 2015 to 2019 but declined in 2020. Mean annual procedure volume per operator varied significantly by state, between 0 in multiple states and 35 in North Dakota. In 2019, 994 unique operators were identified, with 295 operators documented performing 10 or more procedures (29.68%). Operators performing 10 or more TEER procedures provided 68.46% of all operations in 2019, averaging 20.94 procedures per operator.

Conclusions: TEER procedures are becoming increasingly common as more operators are being trained. However, significant variability exists in the procedural volume per operator.

KEYWORDS

mitral regurgitation, operator volume, procedural trends, regional disparities, transcatheter edge-to-edge repair

1 | INTRODUCTION

Transcatheter edge-to-edge repair (TEER) devices were initially approved in 2013 for the treatment of primary mitral regurgitation (MR). Indications for TEER use have expanded to include individuals with secondary MR,¹ increasing the number of eligible patients.

Recent studies have demonstrated a positive relationship between hospital and surgeon volume on morbidity and mortality outcomes, device longevity, and repair rates.² Consequently, the Centers for Medicare and Medicaid Services (CMS) have established institutional and operator requirements for the utilization of TEER. Despite the importance of access to adequate procedure volume, individual state

TEER operator volumes have not been well described. We sought to explore nationwide operator volume trends and geographic variation in access to TEER.

2 | METHODS

The United States CMS Medicare Provider Utilization and Payment Database (MPUPD) was analyzed between 2015 and 2020 for initial TEER procedures (CPT code 33418). The MPUPD is an administrative, claims-based repository that includes 100% of services rendered to Medicare patients enrolled in a fee-for-service program. Claims data are available for providers including name, national provider identifier number, and total procedure volume. Procedures were counted if an operator was the primary or secondary provider on the claim's submission. Procedure volume was identified by the total number of services rendered by an operator. Descriptive statistics were used to identify procedural and operator trends. The calendar year 2019 was used to calculate mean statistics to avoid the effect on healthcare utilization in 2020. State population estimates were classified using 2019 US Census Bureau data. This study was deemed exempt from institutional review as it utilizes publicly available, deidentified data.

3 | RESULTS

Between 2015 and 2020, 22,379 TEER procedures were performed by 444 unique providers who completed at least 10 operations each. Procedure volume increased yearly from 1,176 in 2015 to 6,176 in 2019. Additionally, total operators increased yearly from 60 in 2015 to 295 in 2019. Both procedure volume and total operators decreased in 2020 to 5,315 and 275, respectively. Yearly trends in total operation volume and quantity are provided in Figure 1. The highest 5% of operators (n = 15) performed a median of 54 (interquartile range [IQR]: 46–66) procedures in 2019, with an average Medicare payment per procedure of \$1,128.78 (95% CI: \$1,095.48–\$1,162.07).

TEER procedure and operator volume by state are presented in Table 1 for the calendar year 2019. Mean annual procedure volume per operator varied significantly by state, between 0 in multiple states and 35 in North Dakota (Figure 2). Mean operators per 1,000 population varied between 0 and 7.3 (Figure 3). In 2019, 994 unique operators were identified, with 295 operators documented performing 10 or more procedures (29.68%). Operators performing 10 or more TEER procedures provided 68.46% of all operations in 2019, averaging 20.94 procedures per operator.

4 | DISCUSSION

A significant increase in overall TEER procedural volume and the number of operators was seen over the studied period. The largest yearly rise was noted in 2019, following the publication of the cardiovascular outcomes assessment of the MitraClip percutaneous therapy for heart failure patients with functional mitral regurgitation trial.³ Increases were seen yearly until 2020, likely associated with the national decrease in procedures that occurred during the coronavirus disease 2019 (COVID-19) pandemic. While utilization of TEER has matured considerably as a nonsurgical mitral valve treatment option during this time, it appears that total procedure volume has largely grown as a result of pre-existing institutions performing more TEER procedures rather than adoption by new institutions.⁴

Consistent with this finding, less than one-third of operators accounted for over two-thirds of TEERs performed nationally in 2019. Total operations and the number of operators performing 10 or more TEERs varied significantly by state. Consequently, patient access to experienced TEER providers may be limited based on geographic location due to their place of residence.



FIGURE 1 Yearly trends in transcatheter edge-to-edge repair (TEER) operators and operations. [Color figure can be viewed at wileyonlinelibrary.com]

 TABLE 1
 Procedural and operator volume by state.

	Providers with 10+ procedures			All providers		
	Total operations	Unique operators	Mean (SD) operations	Total operations	Unique operators	Medicare beneficiaries enrolled in Part A
Alabama	217	9	24.11 (15.79)	284	24	592,201
Alaska	0	0	0 (0)	0	0	97,028
Arizona	290	10	29 (15.98)	333	24	773,510
Arkansas	122	6	20.33 (6.25)	135	10	461,800
California	896	31	28.9 (23.86)	1,127	83	3,345,023
Colorado	78	5	15.6 (2.3)	145	20	517,432
Connecticut	57	4	14.25 (4.72)	78	11	391,483
Delaware	0	0	0 (0)	0	0	172,177
Florida	666	32	20.81 (10.45)	936	101	2,431,284
Georgia	240	14	17.14 (3.82)	300	29	1,002,734
Hawaii	0	0	0 (0)	0	0	144,397
Idaho	0	0	O (O)	20	4	218,319
Illinois	139	10	13.9 (4.18)	257	38	1,580,301
Indiana	92	5	18.4 (8.96)	103	9	844,966
lowa	42	3	14 (2.65)	66	8	479,913
Kansas	232	8	29 (10.07)	234	9	429,677
Kentucky	0	0	0 (0)	51	15	596,403
Louisiana	34	1	34 (0)	72	10	527,755
Maine	0	0	0 (0)	12	6	213,884
Maryland	75	4	18.75 (9.74)	113	13	894,762
Massachusetts	141	7	20.14 (5.34)	250	31	987,331
Michigan	94	6	15.67 (2.73)	183	29	1,182,804
Minnesota	152	7	21.71 (10.06)	266	32	547,840
Mississippi	56	3	18.67 (6.66)	76	9	472,384
Missouri	103	7	14.71 (4.19)	189	26	760,580
Montana	90	4	22.5 (11.09)	102	7	184,028
Nebraska	47	3	15.67 (3.21)	73	10	284,077
Nevada	39	3	13 (1.73)	69	7	325,023
New Hampshire	13	1	13 (0)	29	5	241,062
New Jersey	98	6	16.33 (4.63)	141	22	1,100,442
New Mexico	11	1	11 (0)	20	7	259,839
New York	557	25	22.28 (14.94)	709	65	2,060,462
North Carolina	111	6	18.5 (4.72)	218	26	1,223,902
North Dakota	35	1	35 (0)	38	3	105,650
Ohio	142	7	20.29 (7.52)	247	33	1,305,394
Oklahoma	81	5	16.2 (5.5)	121	13	570,557
Oregon	45	3	15 (3.61)	111	16	465,244
Pennsylvania	94	6	15.67 (3.98)	277	47	1,542,946

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TABLE 1 (Continued)

	Providers with 10+ procedures			All providers		
	Total operations	Unique operators	Mean (SD) operations	Total operations	Unique operators	Medicare beneficiaries enrolled in Part A
Puerto Rico	0	0	O (O)	0	0	47,190
Rhode Island	20	1	20 (0)	23	2	117,051
South Carolina	128	5	25.6 (10.36)	153	12	738,559
South Dakota	0	0	O (O)	11	3	136,445
Tennessee	236	13	18.15 (7.53)	294	30	801,641
Texas	285	16	17.81 (6.49)	445	53	2,443,622
Utah	59	2	29.5 (14.85)	71	7	245,321
Vermont	0	0	O (O)	14	2	128,473
Virginia	196	7	28 (23.4)	273	28	1,146,734
Washington	110	4	27.5 (17.67)	159	16	887,074
West Virginia	0	0	O (O)	17	5	284,365
Wisconsin	53	4	13.25 (1.71)	125	21	653,873
Wyoming	0	0	O (O)	0	0	103,991
United States (Total)	6,176	295	20.94 (12.78)	9,021	994	37,068,953

Mean Annual Procedure Volume per Operator in 2019



FIGURE 2 Mean procedure volume per operator. [Color figure can be viewed at wileyonlinelibrary.com]

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Mean Operators per 1,000 Population in 2019 NH, 7.3 VT. 0 ND 12.8 MN 1.8 SD NY WY BL 9.1 CT 28 PA IA 3.1 NJ. 1.1 OF - DE. 0



FIGURE 3 Mean operators per state population. [Color figure can be viewed at wileyonlinelibrary.com]

This variation in access may also play a significant role in training operators. Programs wishing to utilize TEER must perform at least 25 mitral valve surgical procedures, of which 10 must be mitral valve repair, and have at least two cardiothoracic surgeons experienced in valvular surgery.⁵ For educational competency, the 2023 American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions guidelines detailed a minimum of 20 TEER procedures that fellows must complete.⁶ With high-volume centers performing a majority of TEER cases,⁴ training programs at hospitals with minimal operational output may struggle to provide the required caseload for certification; programs located in rural or low-income areas may be affected more by the influence of disparities and availability. For programs that can meet minimum requirements, an operator's mastery may still be heavily influenced by overall operational volume.

Even after sufficient training, nearly 30% of operators performed less than 10 TEER procedures each year. This raises potential concerns regarding the competency of some operators, given that operator experience is associated with greater case volume. For example, prior studies have demonstrated steady improvements in TEER procedural success, case time, and complication rates out to 200 lifetime cases.⁷ Additionally, Adamo et al. observed that institutional volume acts as an independent predictor of optimal procedural results with centers performing greater than 20 procedures each year experiencing better outcomes.⁸ In the setting of these known volume-outcome relationships, the question arises how to establish regional access to experienced TEER facilities for patients while simultaneously ensuring that operators achieve the appropriate caseload required for competency.

Since high-volume centers are associated with better outcomes.² engineered safety processes, and procedural strategies may help mitigate the outcomes in areas with less expertise. This is especially important for training programs and low-income or otherwise disadvantaged areas. Thus, it is important to balance safety with equity for patients who qualify for TEER. Further research is needed to analyze and describe the effect of these strategies on outcomes in low-volume areas.

4.1 Limitations

The inherent nature of this database limits our study. Operations and operators were identified only through their interaction with Medicare beneficiaries; thus, procedures were not identified and attributed to operators if the patient was not receiving Medicare benefits. Operators might not have received credit if more than two operators were present during the operation. Finally, operators with less than 10 TEERs per year were excluded from the analysis, which may affect those in newly commenced programs.

CONCLUSION 5

TEER procedures are becoming increasingly common as more operators are being trained. However, significant variability exists in the procedural volume per operator. Furthermore, access to TEER is

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inconsistent between states, potentially limiting access for patients and physician training. Finally, low-volume operators account for a significant quantity of operations performed, which may influence outcomes.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Steven Imburgio bhttp://orcid.org/0000-0003-4963-5931 Brett Sealove http://orcid.org/0000-0002-8417-8302

REFERENCES

- Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American college of Cardiology/American heart association joint committee on clinical practice guidelines. *Circulation*. 2021;143(5):e72-e227. doi:10.1161/CIR.00000000000923
- Ben-Shoshan J, Overtchook P, Buithieu J, et al. Predictors of outcomes following transcatheter edge-to-edge mitral valve repair. JACC: Cardiovasc Interv. 2020;13(15):1733-1748. doi:10.1016/j.jcin. 2020.03.025
- Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter mitralvalve repair in patients with heart failure. N Engl J Med. 2018;379(24):2307-2318. doi:10.1056/NEJMoa1806640

- Abdelfattah OM, Saad AM, Hisung I, et al. Temporal trends of transcatheter edge-to-edge repair of the mitral valve short-term outcomes in the United States: nationwide representative study. *Structural Heart.* 2021;5(3):279-286. doi:10.1080/24748706.2021. 1883204
- Centers for Medicare and Medicaid Services. NCD-transcatheter mitral valve repair (TMVR) (20.33). Accessed March 2, 2023. https:// www.cms.gov/medicare-coverage-database/view/ncd.aspx? NCDId=363&ncdver=1
- Bass TA, Abbott JD, Mahmud E, et al. 2023 ACC/AHA/SCAI advanced training statement on interventional cardiology (coronary, peripheral vascular, and structural heart interventions): a report of the ACC competency management committee. *Circ Cardiovasc Interv.* 2023;16(0):e000088. doi:10.1161/HCV. 00000000000088
- Chhatriwalla AK, Vemulapalli S, Szerlip M, et al. Operator experience and outcomes of transcatheter mitral valve repair in the United States. JACC. 2019;74(24):2955-2965. doi:10.1016/j.jacc.2019. 09.014
- Adamo M, Pagnesi M, Popolo Rubbio A, et al. Predictors of optimal procedural result after transcatheter edge-to-edge mitral valve repair in secondary mitral regurgitation. *Catheter Cardiovasc Interv.* 2022;99(5):1626-1635. doi:10.1002/ccd.30062

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