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## SUMMARY

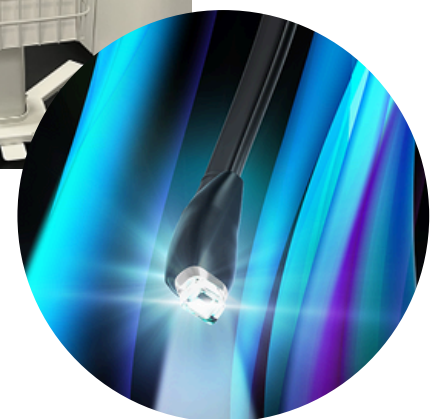
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The Visura Technologies TEECAD® System uses a disposable camera that seamlessly connects to a transesophageal echocardiogram (TEE) probe. The system produces a high-resolution, real-time direct visualization of the laryngeal/esophageal/gastric environment promoting safer intubation and a more efficient and effective TEE probe placement. Case-level clinical procedure information was collected from over 50 physician users at 15 sites across the US to better understand the real-world experience using the TEECAD to assist TEE probe placement.

## BACKGROUND

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Transesophageal echocardiography has become a well-established diagnostic tool for assessment of cardiac pathologies<sup>1,2</sup> and an important adjunct in the planning and execution of both surgical and percutaneous cardiac interventions.<sup>3</sup> Common indications for use of TEE as a diagnostic test include valvular heart disease, percutaneous structural heart interventions, infective endocarditis, assessment for thrombus in atrial fibrillation or flutter, and aortic pathologies.<sup>4,5</sup> TEE is routinely used in open heart surgeries, including more than 60% of CABG surgeries, and over 90% of non-CABG cardiac surgeries.<sup>6</sup> The use of TEE in US CABG procedures grew from 39.9% in 2011 to 62.1% in 2019.<sup>7</sup> Given its ability to deliver high-quality and real-time images without the need for additional x-ray exposure, the use of 3D TEE represents a significant advance in ultrasound imaging guidance<sup>8</sup> and is the mainstay of imaging in catheter-based structural heart interventions.<sup>9,10</sup>



Most contraindications for TEE placement are related to either bleeding concerns or anatomical changes to the GI tract that would make insertion more difficult or more likely to result in a complication. Structural abnormalities associated with challenging placement of a TEE probe include extrinsic compression of the esophagus, esophagitis, tortuous distal esophagus, prior esophageal surgery or radiation, esophageal strictures or fistula, esophageal atresia, hypopharyngeal diverticula and hiatal hernia.<sup>11</sup> TEE probe placement failure associated with difficult probe placement has been reported to range from 0.18% to 1.9% including catastrophic complications of pharyngeal and esophageal perforation.<sup>1,12</sup>

While video laryngoscopes are being used to assist in TEE probe placement, similar to their application in endotracheal intubation, they provide only a constant image of the esophageal inlet as the TEE probe is advanced. In contrast, the TEECAD camera travels with the probe to provide a real-time, dynamic image of the oropharyngeal and esophageal anatomy. By providing the ability to directly visualize the tissue in the path of the probe during insertion and surrounding the TEE probe during intubation, the Visura TEECAD System allows the physician to identify abnormalities and to adjust their approach to enhance procedural success and avoid complications.

Video laryngoscopes have been proven to assist endotracheal intubation due to similar anatomical concerns. This technique has also been utilized for transesophageal intubation with limitation, providing only a constant image up to the hypopharynx. In contrast, TEECAD, commercially available since 2018 and refined in 2023, provides dynamic imaging of the entire traversed course of the TEE probe. The enhanced capacity of TEECAD vs laryngoscopy provides physicians with an increased ability to adapt to anatomical challenges. To understand the real world impact on TEE procedures, Visura captured case-level information on TEECAD System use through the form of a user questionnaire. This information provides a snapshot of device performance as the system achieves greater adoption in TEE imaging procedures.

## **METHODS**

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Procedural and user data was collected during and after the TEECAD procedure by Visura clinical staff in conjunction with the cardiologists' input using a standardized questionnaire from May 2024- August 2024. Information regarding the site and the TEECAD operators was recorded in addition to the user experience. Identifying patient data was not recorded. The user experience with the TEECAD was evaluated in four categories:

- i. Ability to see the esophageal inlet
- ii. Ability to navigate the inlet with the TEECAD attached to the TEE probe on a 5-point scale ("1" = could navigate at all, "5" = easy navigation)
- iii. Whether the TEECAD was beneficial for the performance of the TEE procedure (i.e., contributing to successful TEE probe placement)
- iv. Estimated time to intubate for successful intubations

In addition, observations of relevant information for each case were recorded, such as unique patient anatomy and procedures used to assist with probe insertion.

## RESULTS

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Case information was collected from 19 attending physicians and 32 fellows over 4 months from 15 sites across the US. Cases were performed in the catheterization lab, echocardiography lab, ICU and the operating room. Data was collected on 108 cases for the ability to see the inlet, 109 cases for the ability to navigate the inlet and determine the benefit of the TEECAD to the TEE procedure, and 88 cases for the time to successfully intubate the patient with the TEECAD attached to the probe. Cases were excluded from these totals in the analysis if:

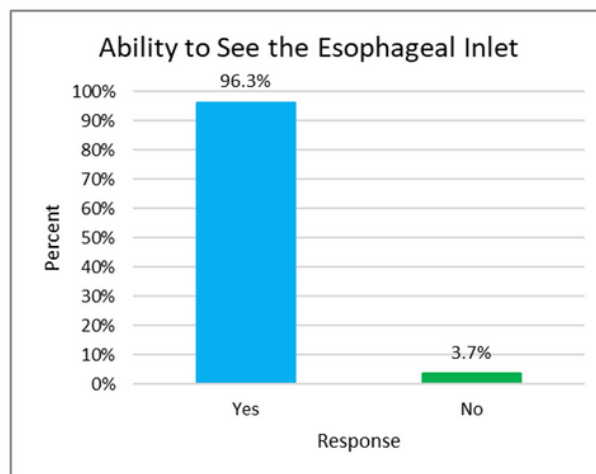
- The case was aborted for a reason not related to the TEECAD
- The TEE probe could not pass through the inlet even without the TEECAD attached
- For the Time to Intubate analysis, intubation was unsuccessful for any reason

### Ability to See the Inlet

Nearly all users (96.3%) were able to clearly see the inlet using the TEECAD. TEE was performed by fellows in two-thirds of the cases (71/107), with attending physicians performing the remaining procedures.

Response	Count	Percent
Yes	103	96.3%
No	4	3.7%
Total	107	100.0%

These results are an improvement compared to those seen with video laryngoscopes. In a study performed by Ishida, et al. comparing use of a McGRATH MAC video laryngoscope to a Macintosh laryngoscope for TEE placement in anesthetized patients, the esophageal inlet was visible in 88% of patients using the McGRATH MAC scope, compared to only 41% of patients using the Macintosh scope.<sup>13</sup> Borde et al. found similar results in TEE placement, with the lowest (best) Cormack-Lehane scores for visualization reported in 87% of cases using a Medicam video laryngoscope and only in 66% of cases with a Macintosh-type scope.<sup>14</sup> Similar differences between video and non-video laryngoscopes are also seen in eight studies of tracheal intubation included in a meta-analysis by Hoshijima et al.<sup>15</sup> (2023).

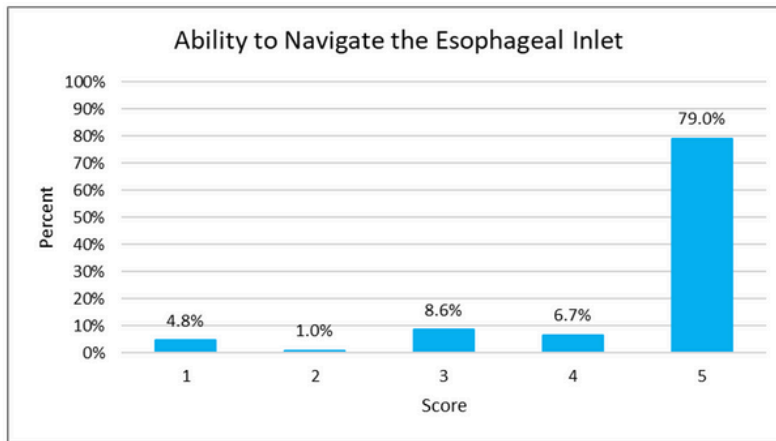


## Ability to Navigate the Esophageal Inlet

Navigation of the inlet with the TEECAD received the highest score of “5” in nearly 8 of every 10 cases (79.0%). All six of the cases rated a “1” or a “2” were performed by fellows who were unable to pass the TEECAD through the inlet. The remaining 16 cases received a rating of “3” or “4”, often requiring more than one attempt or additional manipulation such as a chin thrust or retroflexion.

Video laryngoscopes can provide visualization of the esophageal inlet, but the image is stationary. Since the TEECAD camera travels with the tip of the probe, the physician can rely on real-time positional information to decide on how best to navigate the inlet. The unique ability of the TEECAD System to assess navigation during TEE probe intubation prevents the comparison of data to other visualization systems.

Score	Count	Percent
1	5	4.8%
2	1	1.0%
3	9	8.6%
4	7	6.7%
5	83	79.0%
Total	105	100.0%

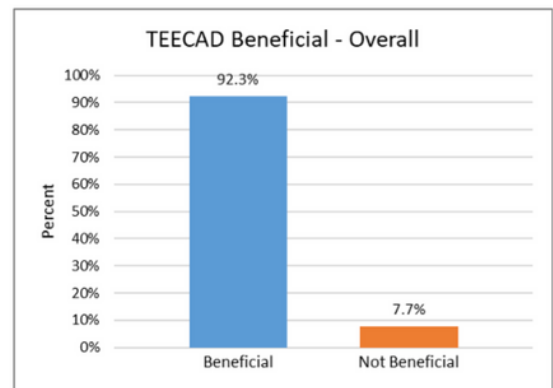


## Beneficial for Probe Placement

Users found the TEECAD to be beneficial for probe placement in nearly all cases (92.3%). In the three cases where the TEE probe could only pass through the inlet without the TEECAD, the users stated that the image provided by the TEECAD of a small but unobstructed inlet still contributed to the success of the procedure.

Six of the eight cases where the TEECAD did not appear to provide a benefit were performed by a user experiencing the TEECAD for the first time. Seven of these eight cases were performed by fellows.

Overall		
TTI	Count	Percent
Beneficial	96	92.3%
Not Beneficial	8	7.7%
Total	104	100.0%

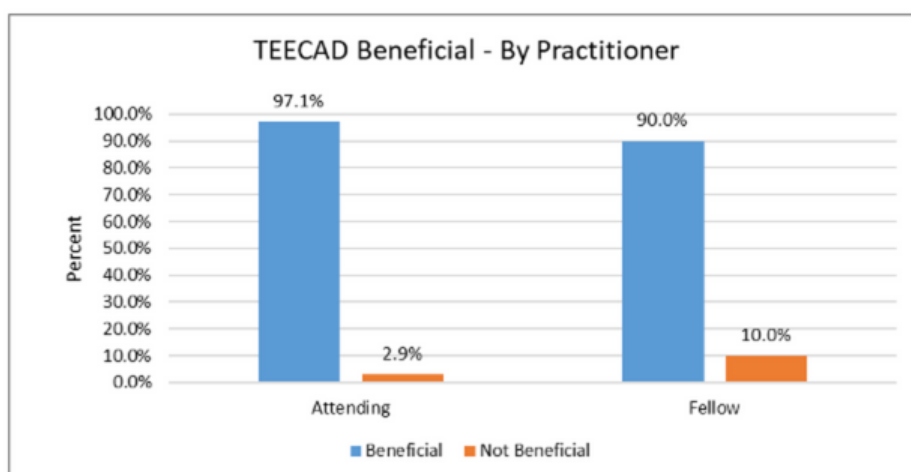




The fellows in this survey can be considered as novices at esophageal intubation. While studies evaluating successful intubation rates by novices have focused on endotracheal intubation, these studies can offer context for the 90.0% rate of successful probe placement seen in this survey. In their meta-analysis of 16 individual studies, Hoshijima et al.<sup>14</sup> found an overall intubation success rate of 89.6% using a video laryngoscope compared to 71.9% with a non-video laryngoscope.

Attending Physician		
TTI	Count	Percent
Beneficial	33	97.1%
Not Beneficial	1	2.9%
Total	34	100.0%

Fellow		
TTI	Count	Percent
Beneficial	63	90.0%
Not Beneficial	7	10.30%
Total	70	100.0%



## USER OBSERVATIONS

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A number of users commented on the features and performance of the TEECAD System:

- Images were helpful for an inlet location that was “bouncing around” and would use the TEECAD on almost all TEEs if they had access to it.
- In a patient with very swollen oral anatomy, the inlet was visualized with the TEECAD and the physician felt confident to push the probe through the resistance.
- The patient was resisting the probe during the entire insertion, so seeing the inlet helped a great deal.
- The inlet was visualized in the presence of extra tissue. The intubation was difficult, but the patient commented “This was much better than last time”.
- Seeing the inlet and knowing it was small but otherwise OK gave him the confidence to keep trying to intubate, which was successful.
- Difficult intubation required a chin thrust and probe maneuvering. The physician felt more confident in pushing since he knew where the probe was located.

The most common impact noted by the users was on their confidence in advancing the probe in cases where they might otherwise have had to abort, either by knowing that there were no obstructions or by having a greater awareness of the probe location within the anatomy.

## CONCLUSION

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The TEECAD System was able to visualize and successfully navigate the esophageal inlet in the vast majority of cases of TEE intubation in our study. The attending physicians found that using the TEECAD System was beneficial for TEE probe placement in nearly all cases, while the cohort of cardiology fellows found benefit in 90% of cases performed. This result likely reflects the expected lower level of procedural experience by physicians in training similar to results seen in novices performing endotracheal intubations. Much of the benefit experienced by the users resulted from visual confirmation of an unobstructed path to the esophageal inlet thanks to the dynamic, real-time direct visualization provided by the TEECAD System, as opposed to the current standard of blindly advancing the probe.

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