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A Comparison of the Accuracy of WATCHMAN Device Sizing Between CT, TEE and Patient Specific 3D Models

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Objective: Determine the accuracy and reliability of CT imaging and CT-based patient specific 3D models of the left atrial appendage for the preprocedural planning of WATCHMAN device implantation in comparison to TEE

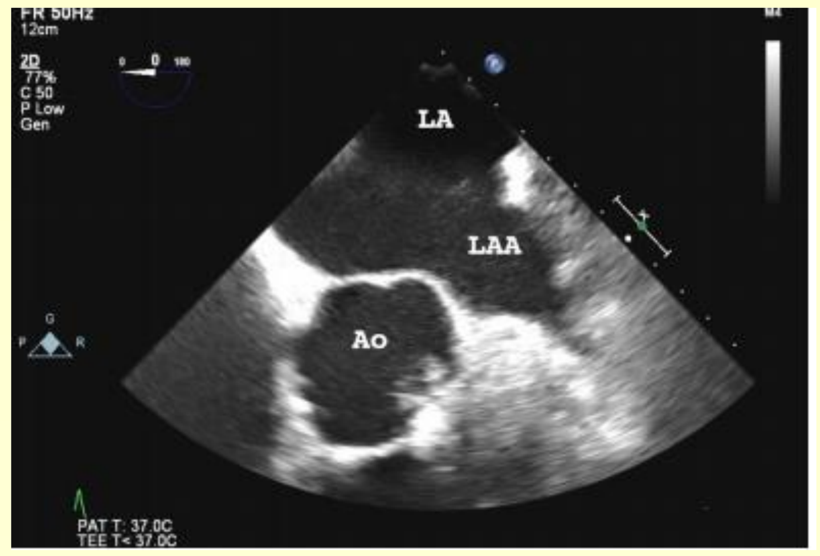
Background

- **Atrial fibrillation (AF) present in 1-2% of general population[1]**
- **Risk of stroke in patients with AF increased by a factor of five[2]**
- **Approximately 90% of thromboembolisms in patients with non-valvular AF are formed in the left atrial appendage (LAA)[3]**
- **Current first line treatment for stroke risk reduction is oral anticoagulation pharmacotherapy[4]**
- **Many patients are contraindicated for anticoagulant therapy for a variety of reasons[4]**
- **Alternative intervention is occlusion of the LAA with the WATCHMAN device. The WATCHMAN device has been shown to be non-inferior to anticoagulants in stroke risk reduction[1]**
- **Device sizing is difficult due to variability of LAA anatomy. Transesophageal echocardiography (TEE) is standard, but presents limitations and challenges**
- **Computerized Tomography (CT) and CT-based 3D models may offer more accurate depiction of LAA**
- **More accurate sizing will potentially reduce material use, procedure time, radiation, and indirectly, risk of intraoperative complications**

Materials & Methods

- **32 patients selected from Parkview Physicians Group – Cardiology that underwent the WATCHMAN procedure**
- **TEE measurements of LAA maximum orifice diameter collected from LAAO Registry supplied by Parkview Heart Institute**
- **CT Scans evaluated retrospectively to measure LAA maximum orifice diameter using Philips Intellispace Portal v9.0 (Philips Medical Systems, Andover, MA)**
- **Use 3D CT imaging to segment patient specific LAA and print with Form 2 3D printer**
- **Measure LAA maximum orifice diameter of 3D models**
- **Used paired T-tests to compare measurements taken with each method**
- **Compare predicted device sizes in each group with actual device size implanted**

Imaging and Models



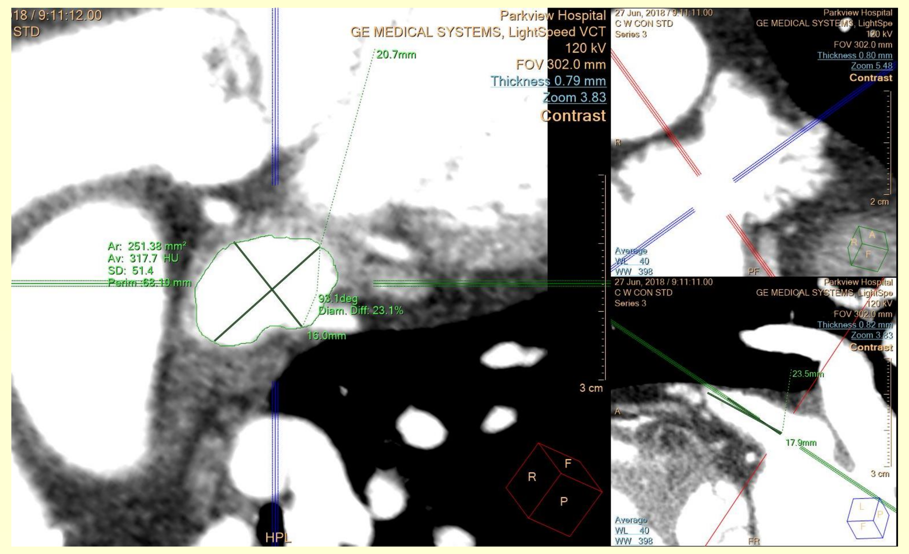


Figure 1: Imaging and modeling used for measuring the LAA (from left to right: TEE, CT, 3D models)

Results

Table 1: Patient Procedural Characteristics (n=32)

Age (mean yrs ± sd)	72.88 ± 7.08
Body Mass (mean kg ± sd)	96.92 ± 26.46
Male	17
Female	15
HTN	30
Diabetes Mellitus	14
Vascular Disease	14
Stroke	12
Heart Failure	9
Thromboembolism History	4
TIA	2

Table 2: Indications for Procedure

History of major bleed	25
High fall risk	11
Increased thromboembolic stroke risk	12
Patient preference	30
Non-compliance with anticoagulation therapy = 5	5
> 2 indications for WATCHMAN	32
> 3 indications for WATCHMAN	17

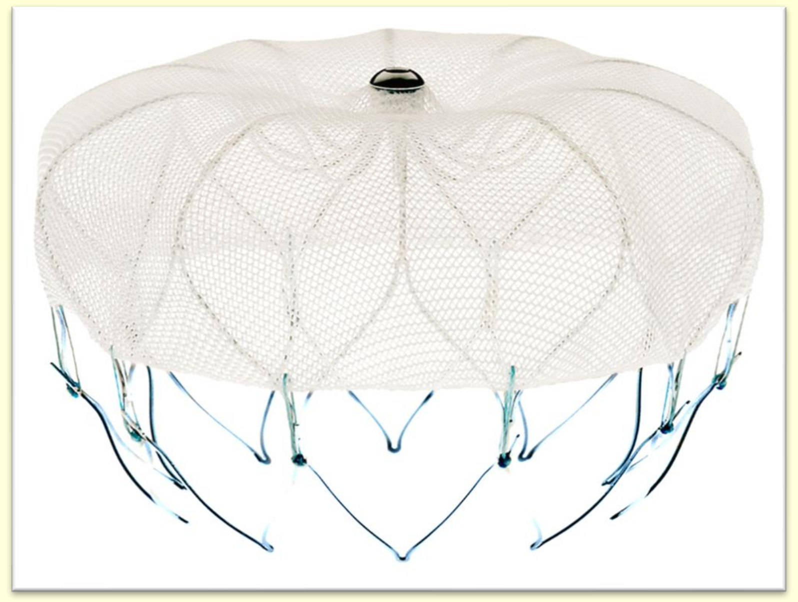


Figure 2: WATCHMAN device

Table 3: Mean differences between measurements of each LAA using 3D models, CT images, and TEE

	Mean difference (mm)	p-value
3D model – TEE	**3.4 ± 3.1**	**< 0.00001**
CT – TEE	**4.2 ± 3.5**	**< 0.00001**
3D model – CT	-1.0 ± 2.3	0.02551

(mean difference ± sd)
Red values indicate statistical significance at α = 0.05

Table 4: Difference between size recommendation and size deployed in number of device sizes (i.e. difference between a 27mm device and a 24mm device is 1 device size)

	Mean difference (in number of device sizes)	p-value
3D Models	0.6 ± 0.8	0.00011
CT	0.7 ± 0.9	0.00007
TEE	-0.6 ± 0.8	0.0002

(number of device sizes ± sd)
Red values indicate statistical significance at α = 0.05

Figure 3: Device Size Recommendations in Comparison to Device Sizes Deployed

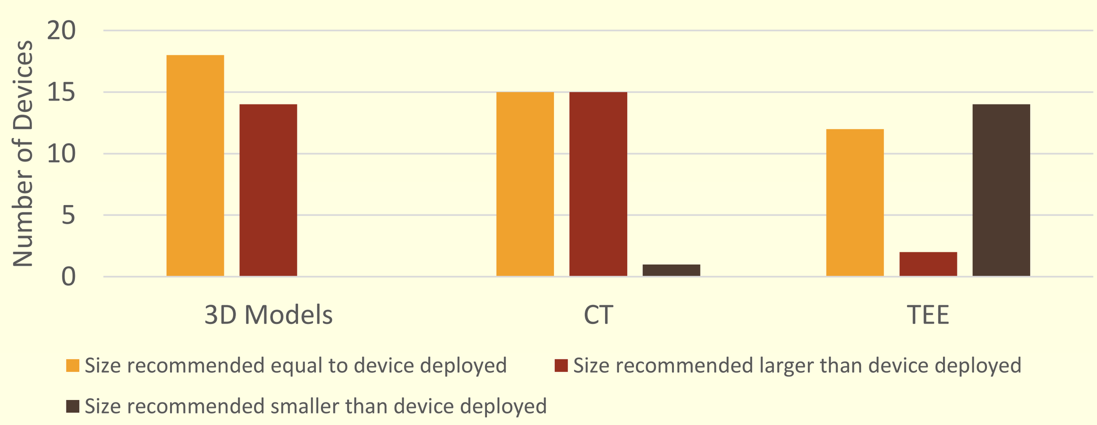
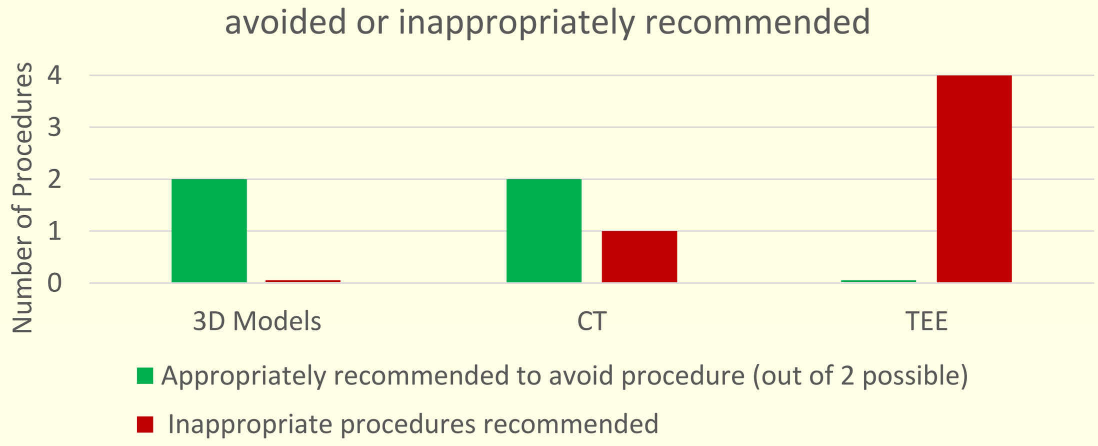


Figure 4: Procedures that would have been appropriately avoided or inappropriately recommended



Discussion

- **TEE underestimates the maximum LAA orifice diameter when compared to CT and 3D models**
- **TEE device sizing appears to be the least accurate of the three methods**
- **Device sizing from CT and 3D models, on average, is larger than device size deployed**
- **Suggests that a larger device could have been deployed to cover more of the LAA**
- **Preprocedural planning based entirely on TEE inappropriately recommended the WATCHMAN procedure for four patients with inadequate LAAs**
- **3D models would have helped physicians avoid the two procedures in which the device was not deployable**

Conclusions

- **CT imaging and CT-based 3D models for preprocedural assessment of the LAA and planning of the WATCHMAN procedure appear not only to be accurate methods for correct device sizing, but more accurate than the traditionally used TEE**
- **The use of CT imaging and 3D models helps prevent unnecessary procedures in patients with inadequate LAAs**

References

1. Gloekler S, Meier B, Windecker S. Left atrial appendage closure for prevention of cardioembolic events. Swiss Med Wkly 2016. doi:10.4414/smw.2016.14298.
2. Oladiran O, Nwosu I. Stroke risk stratification in atrial fibrillation: a review of common risk factors. J Community Hosp Intern Med Perspect 2019;9(2):113–20. doi:10.1080/20009666.2019.1593781
3. Majule DN, Jing C, Rutahoile WM, Shonyela FS. The efficacy and safety of the WATCHMAN device in LAA occlusion in patients with non-valvular atrial fibrillation contraindicated to oral anticoagulation: a focused review. Ann Thorac Cardiovasc Surg 2018;24:271–8. doi:10.5761/atcs.ra.18-00014.
4. Holmes DR, Kar S, Price MJ, Whisenant B, Sievert H, Doshi SK, et al. Prospective randomized evaluation of the Watchman left atrial appendage closure device in patients with atrial fibrillation versus long-term warfarin therapy. J Am Coll Cardiol 2014;64(1):1–12. doi:10.1016/j.jacc.2014.04.029

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