Left atrial appendage occlusion in everyday clinical practice

Closing the gap

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Transoesophageal echocardiography guidance with paediatric probes in adults undergoing left atrial appendage occlusion

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INTRODUCTION

Transoesophageal echocardiography (TOE) plays a pivotal role in the guidance of percutaneous left atrial appendage occlusion (LAAO). Visualisation of the positioning and deployment of the LAAO device is essential for a successful and safe implantation[1]. Due to the relatively long duration of an LAAO procedure, currently used standard size probes are often not tolerated by patients without the use of general anaesthesia (GA). The use of GA, however, results in the need for an anaesthesiologist, longer procedure times and the risk of anaesthesia-related complications. Therefore, less invasive imaging techniques to guide LAAO are warranted. For paediatric purposes, smaller TOE probes have been developed the micro probe and the mini probe. Evidence on LAAO guidance with paediatric probes is scarce[2].

METHODS

In this prospective, single-centre registry of consecutive patients undergoing LAAO, the feasibility and safety of paediatric probes (Figure 1) to guide the procedure was analysed. The primary effectiveness outcome was adequate closure according to the manufacturer's instructions for use. The primary safety outcome was the occurrence of probe-related complications.

All procedures were performed by the same experienced operators guided by an expert imaging specialist. Paediatric probe type was chosen at the discretion of the imaging specialist; the first cases were performed with a micro probe (S8-3t; Philips Healthcare, Andover, MA, USA) since the mini probe (S7-3t; Philips Healthcare) was not immediately available. After introduction of the mini probe, better resolution/colour Doppler resulted in preferential selection of the mini probe. Only conscious sedation (intravenous diazepam) and local anaesthetics (lidocaine) were required; however, by design the first cases were performed with GA. A standard set of images was obtained measuring the left atrial appendage (LAA). Combined fluoroscopy imaging and TOE measurements were used for optimal sizing of the LAAO devices[1]. All patients underwent follow-up imaging with a standard TOE probe using local anaesthetics only in order to verify adequate device positioning.

Statistical analyses were performed as appropriate using SPSS statistical software, Version 24 (IBM Corp., Armonk, NY, USA). P-values of <0.05 were considered statistically significant.

Figure 1. Specifications of TOE probes.

	standard TEE (X7-2t)	mini TEE (S7-3t)	micro TEE (S8-3t)
Shaft diameter	9.5 mm	7.4 mm	5.2 mm
Tip diameter	16.6 mm	10.7 mm	7.5 mm
Elements	>2500	48	32
Frequency range	7-2 MHz	7-3 MHz	8-3 MHz
Acquisition	2D, 3D + 180° mechanical rotation	2D + 180° mechanical rotation	2D + 180° mechanical rotation
Shaft length	106cm	70 cm	80 cm

Provided by: Philips Healthcare, Andover USA.

RESULTS

A total of 86 patients (age 72.6±6.7 years, 65% male) were included (Supplementary Figure 1). In 28 (33%) patients, LAAO was combined with pulmonary vein isolation. CHA_2DS_2-VASc and HASBLED scores were high, 3.8±1.6 and 3.0±1.2 respectively. All baseline characteristics are shown in Supplementary Table 1. Two types of LAAO device were used; 77 (90%) patients received a WATCHMAN™ device (Boston Scientific, Marlborough, MA, USA) and 9 (10%) patients received an AMPLATZER™ Amulet™ (Abbott Vascular, Santa Clara, CA, USA). The procedural characteristics are presented in Supplementary Table 2. In 77 (90%) patients, successful implantation was achieved. Seven of nine failed implantations were due to anatomical reasons (Supplementary Figure 1). One other procedure was complicated by atrial perforation causing tamponade, which required successful surgical intervention. However, this patient died within 48 hours because of intractable haemodynamic shock. The last procedure was interrupted because of LAA thrombus. Another patient developed thrombus on the sheath during the procedure. After additional administration of heparin, the thrombus resolved and the procedure could be completed.

The micro and mini probes were used in 42 (49%) and 44 (51%) patients, respectively. The insertion of both probes was successful in all cases. No procedure was prematurely terminated because of discomfort of the patient, and no conversion to GA was needed in any patient. One patient had a minor oropharyngeal bleeding during the procedure, managed conservatively. In all cases, image quality was sufficient to complete the procedure, and switching between probes was not necessary. No traumatic injuries to the oropharyngeal space or the upper gastrointestinal tract were reported. One patient experienced mild discomfort of the oesophagus during hospitalisation. Complete closure was achieved in 60 (78%) patients; minimal residual flow was

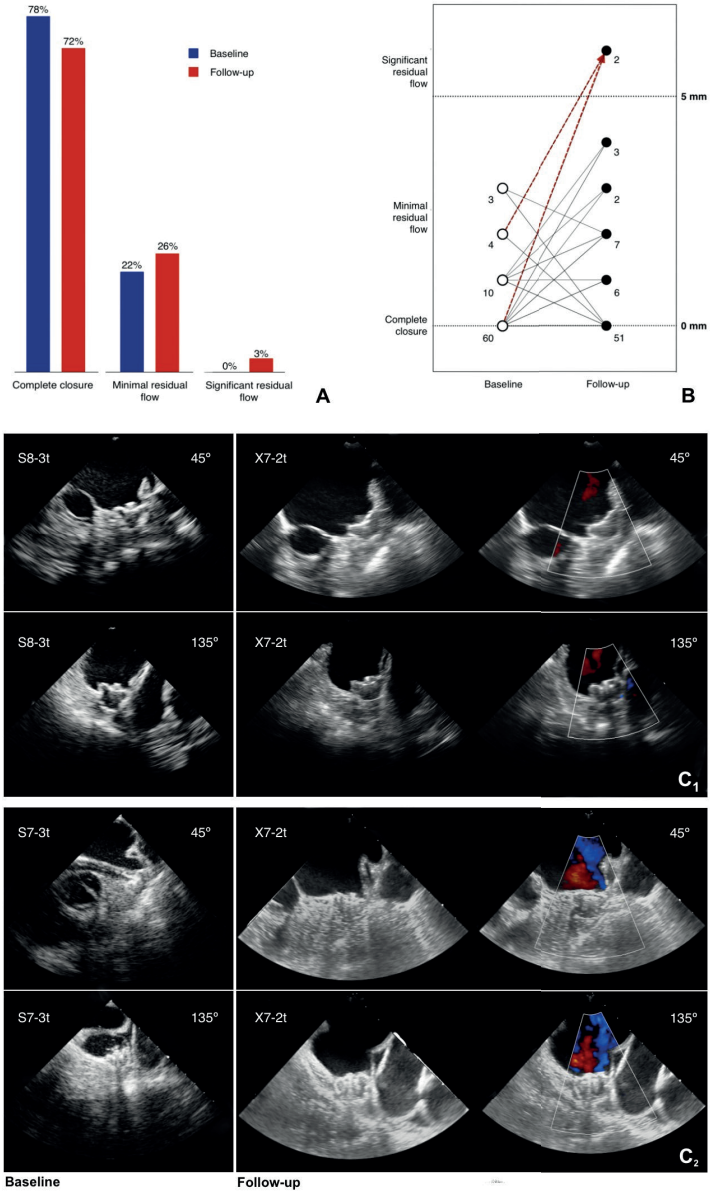
present in 17 (22%) patients. All echocardiographic findings are described in Supplementary Table 3. No substantial differences between the paediatric probes were found.

Follow-up imaging was performed in 72 (95%) patients. Complete closure was observed in 51 (72%) patients, while minimal residual flow was seen in 18 (25%) patients. Significant residual flow was observed in only two patients. One WATCHMAN device embolization to the abdominal aorta was observed during follow-up TOE, resulting in adequate closure in 69 (96%) patients during follow-up. Differences between baseline and follow-up peri-device leakage are illustrated in Figure 2; most shifts did not lead to significant residual flow. In 63% of all patients there was no change in peri-device leak, while 26% of the patients showed an increase and 11% showed a decrease. An average increase of 0.37 mm peri-device leakage was calculated between LAAO and follow-up imaging. One patient showed device-related thrombus while still using anticoagulation, but no evidence of thrombo-embolic complications was present.

DISCUSSION

Our study is the largest series to date describing the use of paediatric probes in adults for guiding LAAO, with the highest number of procedures performed without GA and with closure rates during follow-up imaging available. The study demonstrated that the guidance of LAAO with paediatric probes can be performed without probe-related complications, and without the need to convert to GA in any patient. Adequate closure was observed in all patients during the procedure and in 96% of all patients during follow-up imaging.

Figure 2. Differences between baseline with paediatric probes and follow-up imaging with a standard probe.



A) Peri-device leakage at baseline and at follow-up. B) Shifts of peri-device leakage between baseline and follow-up. C) Typical examples of micro (1) and mini (2) probe images during LAAO compared to follow-up using a standard probe.

In our study, successful LAAO was observed in 90% of all patients, which is somewhat lower compared to recently published observational studies (e.g., EWOLUTION; success rate 98.5%)[3]. A possible explanation is that in the current study population no imaging was performed prior to LAAO to eliminate cases with unsuitable anatomy. Of note, none of the failed procedures was due to inadequate visualisation during the procedure, as indicated by the operating cardiologist and imaging cardiologist.

The findings in the present study are consistent with results from previous reports on the feasibility of paediatric probes to guide transcatheter interventions in adults. Recently Barreiro-Perez et al reported on 50 LAAOs under micro probe guidance without GA. Good tolerance of the micro probe and no probe-related complications were presented, similar to our results[2].

In the current study, a small increase of peri-device leakage was observed at follow-up imaging performed with the standard probe compared to procedural findings. However, historical data describe comparable increases of peri-device leakage during follow-up, even when adult probes are used both during the procedure and during follow-up3. Furthermore, the increase in peri-device leakage was rather small (+0.37 mm), resulting in clinically significant peri-device leakage in only two patients.

Limitations

The performance of the adult micro and mini probes was not compared within the same patients. Although our study is the largest of its kind so far, the small sample size limits the power of the analysis. All procedures were guided by the same experienced operators and experienced imaging cardiologist, which may underestimate the potential differences in procedure outcomes with multiple operators and varying levels of experience.

CONCLUSION

The use of paediatric probes in the guidance for LAAO in adults is a safe and effective alternative avoiding the need for GA. Further evaluation and comparison with other imaging modalities should be performed. The image quality of paediatric probes did not influence adequate closure results compared to historical outcome data with adult probes.

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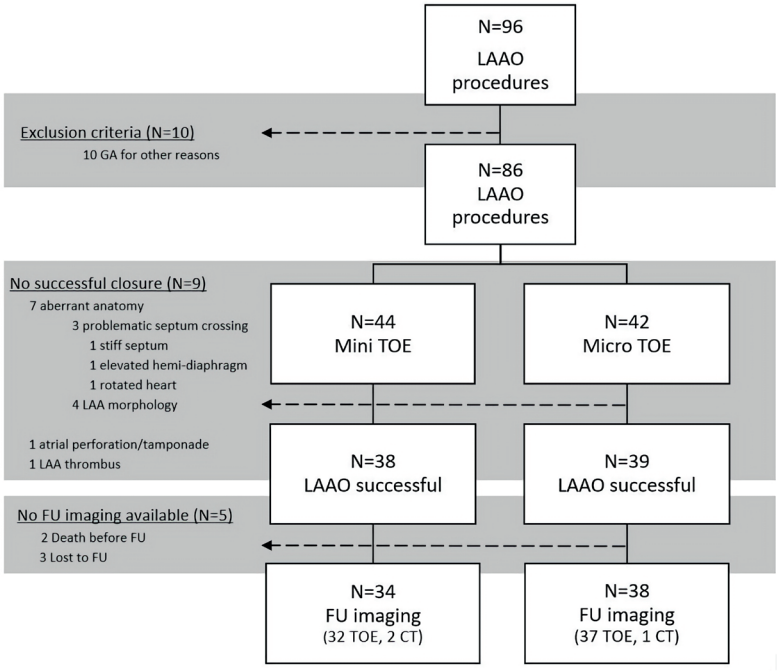
SUPPLEMENTAL MATERIAL

Supplementary figure 1. Flow-chart of patient inclusion



CT = Computed Tomography, FU= follow-up, GA= general anaesthesia, LAA= left atrial appendage, LAAO= Left atrial appendage occlusion, TOE= Transoesophageal echocardiography

Supplementary table 1. Baseline criteria.

	Micro-TOE group (n=42)	Mini-TOE group (n=44)	Total (n=86)	p-value
Age in years	72.6±7.1	72.7±6.3	72.6±6.7	0.938
Gender male (%)	27 (64%)	29 (66%)	56 (65%)	0.875
Indication for WM * (%)				
History of bleeding	34(81%)	32 (73%)	66 (77%)	0.367
High risk of bleeding	2(5%)	1 (2%)	3 (4%)	0.529
Thrombo-embolic event under (N)OAC	6 (14%)	6 (14%)	12 (14%)	0.843
Personal preference	2 (5%)	3 (7%)	5 (6%)	1.000
Other	4 (10%)	6 (14%)	10 (12%)	0.739
Atrial fibrillation type				
Paroxysmal	24 (57%)	19 (43%)	43 (50%)	0.018
Persistent	1 (2%)	10 (23%)	11 (13%)	
Permanent	17 (41%)	15 (34%)	32 (37%)	
CHA_2DS_2-VASc	3.7±1.5	3.9±1.6	3.8±1.6	0.560
≤1	3 (7%)	0 (0%)	3 (4%)	0.137
2-3	6 (14%)	10 (23%)	16 (19%)	
≥4	33 (79%)	34 (77%)	67 (78%)	
HAS-BLED	3.0±1.2	3.1±1.2	3.0±1.2	0.603
<3	13 (31%)	16 (36%)	29 (34%)	0.652
≥3	29 (69%)	28 (64%)	57 (66%)	
Anticoagulation at hospital admission				
None	13 (31%)	11 (25%)	24 (28%)	0.538
APT	15 (36%)	12 (27%)	27 (31%)	0.399
(N)OAC	11 (26%)	18 (41%)	29 (34%)	0.149
(N)OAC+APT	3 (7%)	3 (7%)	6 (7%)	1.000
Anticoagulation at discharge				
None	0 (0%)	1 (2%)	1 (1%)	1.000
APT	5 (12%)	13 (30%)	18 (21%)	0.044
DAPT	12 (29%)	9 (21%)	21 (25%)	0.381
(N)OAC	11 (26%)	15 (35%)	26 (31%)	0.425
(N)OAC+APT	3 (7%)	5 (12%)	8 (9%)	0.714
LMWH+APT	11 (26%)	0 (0%)	11 (13%)	<0.000

Values are mean± standard deviation, median[interquartile range] or n(%).* Some patients have multiple indications. APT= antiplatelet therapy, DAPT = dual antiplatelet, LMWH = low molecular weight heparin, (N)OAC= (novel) oral anticoagulation therapy, TOE= Transoesophageal echocardiography, WM=Watchman.

Supplementary table 2. Procedural characteristics.

	Micro TOE group (n=42)	Mini TOE group (n=44)	Total (n=86)	p-value
Type procedure:				
LAAC combined with PVI	16 (39%)	12 (27%)	28 (33%)	0.359
LAAC	26 (62%)	32 (73%)	58 (67%)	0.736
Type device:	37 (88%)	40 (91%)	77 (90%)	
Watchman	5 (12%)	4 (9%)	9 (11%)	
Amplatzer Amulet				
General anaesthesia	6 (14%)	0 (0%)	6 (8%)	0.011
Rhythm at start device implant				
Sinus rhythm	24 (57%)	24 (55%)	48 (56%)	0.808
Atrial fibrillation	18 (43%)	20 (46%)	38 (44%)	
Duration implantation (min.) *	46±19	49±20	48±20	0.478
Fluoroscopy time (min.)	9±3	9±4	9±4	0.816
DAP ($Gycm^2$)	19 [10.25-32.25]	20.25 [12.50-33.0]	20 [11.0-33.0]	0.387
Mean device size (mm)	25±3	25±4	25±3	0.656
No. of devices used	1 [1-1]	1 [1-1]	1 [1-1]	0.961
No. of partial recaptures	0 [0-1]	0 [0-1]	0 [0-1]	0.915
No. of full recaptures	0 [0-2]	0 [0-1.25]	0 [0-2]	0.507
LAAC completed	39 (93%)	38 (86%)	77 (90%)	0.485

Values are mean± standard deviation, median [interquartile range] or n(%).* Time between venous puncture and sheath removal. DAP=dose-area product, LAAC= Left atrial appendage closure, PVI= pulmonary vein isolation, TOE= Transoesophageal echocardiography, WM=Watchman.

Supplementary table 3. Echocardiographic findings.

		Micro TOE group (n=42)	Mini TOE group (n=44)	Total (n=86)	p-value
Baseline	Successful insertion	42 (100%)	44 (100%)	86 (100%)	-
	Interrupted procedures	0 (0%)	0 (0%)	0 (0%)	-
	Minor probe related complications	0 (0%)	2 (5%)	2 (2%)	0.494
	Diameter ostium LAA in mm				
	0	20±4	21±4	21±4	0.532
	45	19±3	19±3	19±3	0.974
	90	20±3	20±4	20±3	0.964
	135	20±5	21±5	20±5	0.478
	Length LAA in mm				
	0	27±7	26±7	26±7	0.795
	45	27±6	25±7	26±6	0.156
	90	25±6	25±7	25±6	0.937
	135	23±5	23±7	23±6	0.965
	Compression in percentages [*]				
	Min.	12±6	12±7	12±6	0.975
	Max.	20±6	21±6	20±6	0.915
	Peri-device leakage in mm [†]				
	No leakage	33 (83%)	27 (73%)	60 (78%)	0.314
	Minimal residual flow[‡]	7 (17%)	10 (27%)	17 (22%)	
	Significant residual flow [§]	0 (0%)	0 (0%)	0 (0%)	
	Thrombus	0 (0%)	2 (5%)	2 (2%)	0.494
Follow-up	Imaging modality	37 (97%)	32 (94%)	69 (96%)	0.594
	TOE (X7-2t)	1 (3%)	2 (6%)	3 (4%)	
	CT [♦]				
	Duration between FU imaging and LAAC in days	76±19	90±32	83±27	0.025
	Peri-device leakage				
	No leakage	32 (87%)	19 (56%)	51 (72%)	0.013
	Minimal residual flow[‡]	4 (11%)	14 (41%)	18 (25%)	
	Significant residual flow [§]	1 (3%)	1 (3%)	2 (3%)[$]	
	Mean difference leakage in mm	0.22±0.22	0.53±0.28	0.37±0.15	0.377
	Device embolization	1 (3%)	0 (0%)	1 (2%)[$]	1.000
	Device-related thrombus	1 (3%)	0 (0%)	1 (2%)[$]	1.000

Values are mean± standard deviation, median [interquartile range] or n(%).

[*]Measured in successful LAAC by Watchman device at 0, 45, 90 and 135 degrees. [†] Only measured in successful LAAC.

[‡]Watchman ≤5mm, Amplatzer Amulet ≤3mm.

[§]Watchman >5mm, Amplatzer Amulet >3mm.

[♦] CT imaging was performed on the Philips 256-slice Brilliance iCT scanner (Philips Medical Systems, Best, the Netherlands) with a Venae Pulmonalis step and shoot protocol.

[$]Observed with standard TOE probe.

CT = Computed Tomography, FU= Follow-up, LAA= Left atrial appendage, LAAC = Left atrial appendage closure, TOE = Transoesophageal Echocardiography.