Supplementary data

Supplementary Table 1. Sociodemographic characteristics and insurance providers for WATCHMAN patients enrolled in the LAAO Registry between 1 January 2016 and 31 December 2018.

	Total (n=38,1558)	Successful Procedure (n=35,417)	Aborted Procedure (n=1,601)	Canceled Procedure (n=1,140)	*P* Value
Age, yrs	76.1 ± 8.1	76.0 ± 8.1	77.2 ± 7.9	77.2 ± 7.9	<0.0001
Age categories					<0.0001
<55 yrs	496 (1.3)	470 (1.3)	17 (1.1)	9 (0.8)	
55 to 64 yrs	2,303 (6.0)	2,176 (6.1)	78 (4.9)	49 (4.3)	
65 to 74 yrs	12,167 (31.9)	11,422 (32.3)	419 (26.2)	326 (28.6)	
75 to 84 yrs	17,799 (46.7)	16,438 (46.4)	805 (50.3)	556 (48.8)	
≥85 yrs	5,393 (14.1)	4,911 (13.9)	282 (17.6)	200 (17.5)	
Sex					0.3337
Male	22,468 (58.9)	20,844 (58.9)	926 (57.8)	698 (61.2)	
Female	15,672 (41.1)	14,556 (41.1)	675 (42.2)	441 (38.7)	
Race					0.1715
White	35,345 (92.6)	32,805 (92.6)	1,498 (93.6)	1,042 (91.4)	
Black	1,768 (4.6)	1,653 (4.7)	53 (3.3)	62 (5.4)	
Hispanic	138 (0.4)	130 (0.4)	5 (0.3)	3 (0.3)	
Asian	621 (1.6)	565 (1.6)	33 (2.1)	23 (2.0)	
Primary insurance payer					0.8359
Medicare/Medicaid	33,131 (86.9)	30,752 (86.8)	1,389 (86.8)	1,000 (87.7)	
Private health insurance	4,475 (11.7)	4,165 (11.8)	188 (11.7)	122 (10.7)	
Other	542 (1.4)	500 (1.4)	24 (1.5)	18 (1.6)	

(Redrawn with permission from [24])

As part of the FDA approval process for LAAO, a formal national registry was mandated. This registry includes all patients treated with a commercial device. As such, it provides a snapshot of the types of patients that are being treated as well as the outcomes of treatment. As can be seen, such information includes baseline clinical characteristics, racial patterns of care, reimbursement strategies, medical history as well as socio-economic issues which may be important for health care systems.

Supplementary Table 2. Medical history from WATCHMAN patients enrolled in the LAAO Registry between 1 January 2016 and 31 December 2018.

	Total (n=38,1558)	Successful Procedure (n=35,417)	Aborted Procedure (n=1,601)	Canceled Procedure (n=1,140)	*P* Value
CHA_2DS_2-VASc score	4.6 ± 1.5	4.6 ± 1.5	4.6 ± 1.4	4.8 ± 1.5	<0.0001
Congestive heart failure	14,266 (37.4)	13,186 (37.2)	582 (36.4)	498 (43.7)	<0.0001
Congestive heart failure class					
NYHA functional class I	3,477 (9.11)	3,218 (9.09)	147 (9.18)	112 (9.82)	
NYHA functional class II	6,527 (17.11)	6,051 (17.09)	266 (16.61)	210 (18.42)	
NYHA function class III	3,075 (8.06)	2,835 (8.00)	116 (7.25)	124 (10.88)	
NYHA functional class IV	202 (0.53)	179 (0.51)	11 (0.69)	12 (1.05)	
Prior stroke	10,433 (27.3)	9,584 (27.1)	474 (29.6)	375 (32.9)	<0.0001
Prior transient ischemic attack	5,555 (14.6)	5,100 (14.4)	247 (15.4)	208 (18.3)	0.0001
Prior thromboembolic event	7,005 (18.4)	6,453 (18.2)	316 (19.7)	236 (20.7)	0.0005
HAS-BLED score	3.0 ± 1.1	3.0 ± 1.1	3.0 ± 1.1	3.1 ±1.2	0.0118
Other history and risk factors					
Fall risk	15,063 (39.5)	13,951 (39.4)	656 (41.0)	456 (40.0)	0.0418
Cardiomyopathy	8,098 (21.2)	7,459 (21.1)	342 (21.4)	297 (26.1)	0.0018
Ischemic	4,121 (10.8)	3,811 (10.8)	158 (9.9)	152 (13.3)	0.0015
Nonischemic	2,828 (7.4)	2,592 (7.3)	132 (8.2)	104 (9.1)	0.0036
Chronic lung disease	8,101 (21.2)	7,525 (21.3)	338 (21.1)	238 (20.9)	0.9544
Coronary artery disease	18,126 (47.5)	16,824 (47.5)	738 (46.1)	564 (49.5)	<0.5294
Sleep apnea	9,740 (25.5)	9,103 (25.7)	366 (22.9)	271 (23.8)	0.0409
Arrhythmia history					
Atrial fibrillation type					<0.0001
Paroxysmal	19,800 (51.89)	18,566 (52.42)	806 (50.34)	428 (37.54)	
Persistent (>7 days)	8,056 (21.11)	7,489 (21.15)	334 (20.86)	233 (20.44)	
Long-standing persistent (>1 yr)	3,674 (9.63)	3,366 (9.50)	151 (9.43)	157 (13.77)	
Permanent	6,461 (16.93)	5,848 (16.51)	300 (18.74)	313 (27.46)	
Atrial flutter	5,201 (13.63)	4,903 (13.84)	188 (11.74)	110 (9.65)	0.0001

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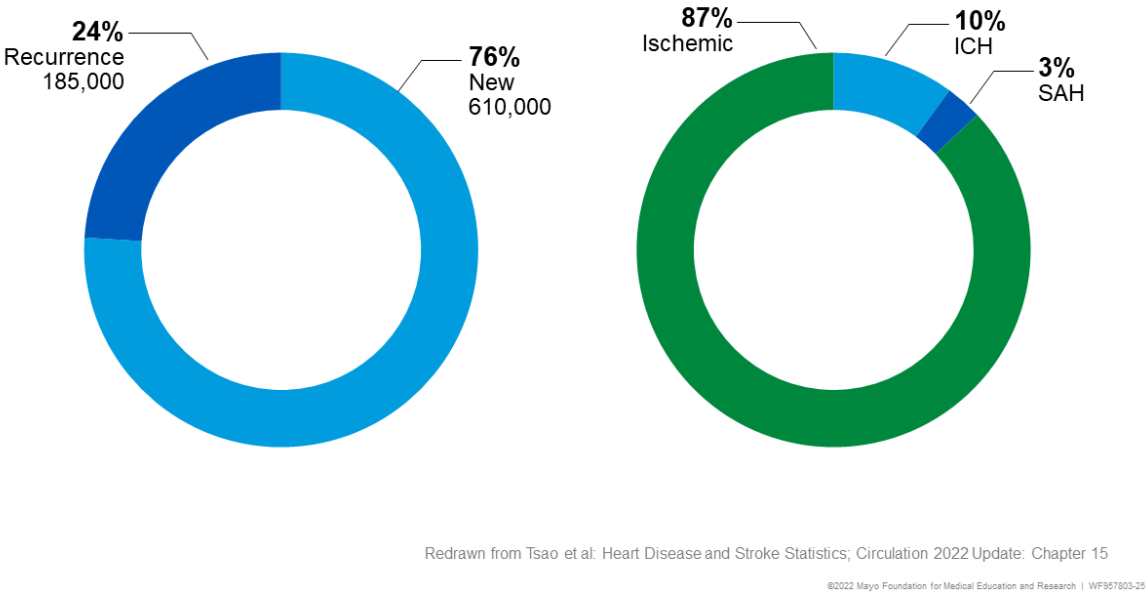
Supplementary Table 3. LAAO devices in development and clinical use.

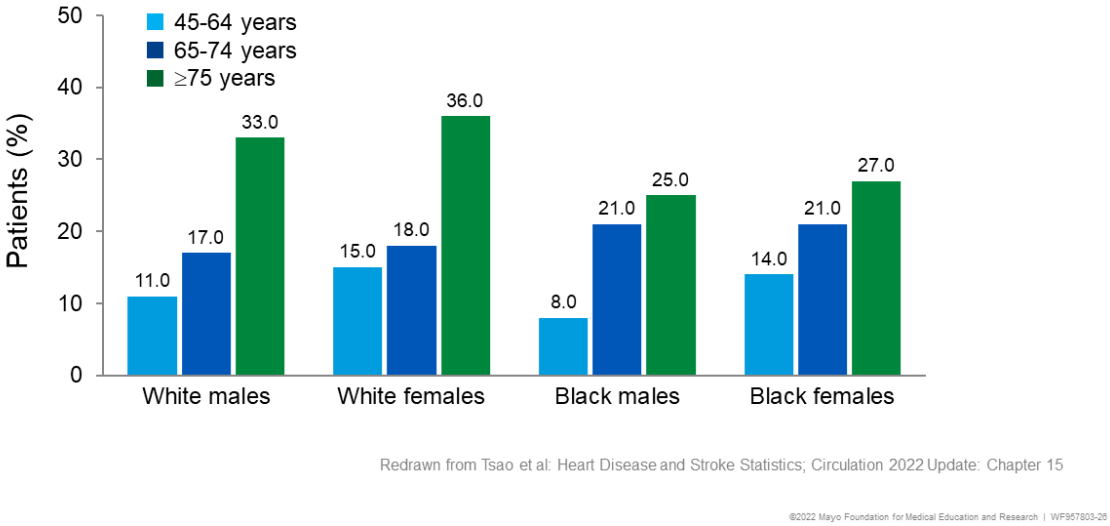
Plug Type	Disk and Lobe	Ligation/Obliteration
Watchman FLX	Amulet	Lariat
WaveCrest	LACbes	LAMINAR
Conformal	SeaLA	TigerPaw pro
Occlutech	Ultraseal	AtriClip
LeFort		Appendligator
LAmbre		

Three broad groups of devices have been explored and undergoing evaluation. The number of devices will continue to increase. Despite the fact that the results of LAAO with both Watchman FLX and Amulet are excellent with acute success rates greater than 95%, there are continued unmet needs which drive the development of new approaches aimed at making the procedures easier safer and more predictable for the increasing number of patients with NVAF. In addition, these newer device may decrease or eliminate DRT or need for anticoagulation as well as decrease residual leaks. Narasimham et al reviewed 12 devices developed for either endocardial or epicardial LAAO[56]. Despite the plethora of new devices, there are still only 5 completed RCT's in the field although others are planned and being performed. Most recently the Conformal device has begun testing



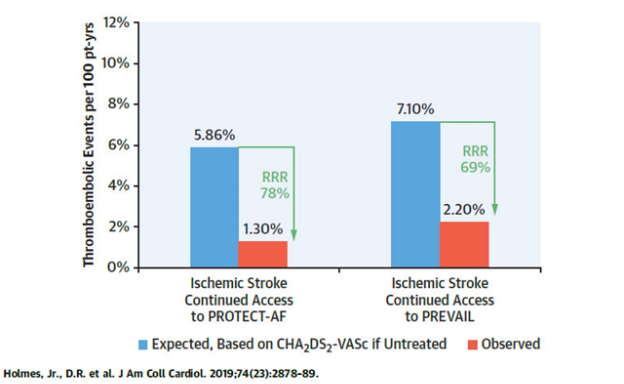
Supplementary Figure 1. Incidence and pathophysiology of stroke.

The most recent data on strokes in the US. Each year approximately 795,000 people have either a first clinical event (610,000) or have a recurrent stroke (185,000). Of the total number of strokes, 87% are ischemic, 10% have an intracerebral haemorrhage, and 3% have a subarachnoid bleed (SAH). (Redrawn with permission from Chapter 15 [106])



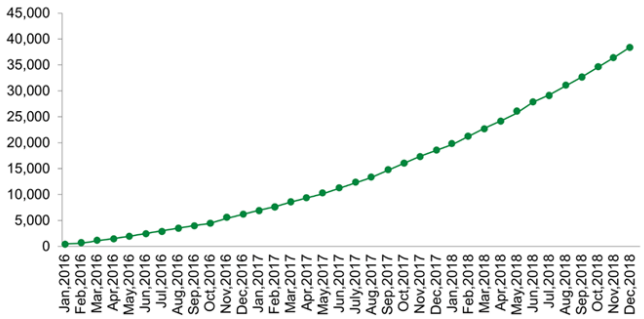
Supplementary Figure 2. Probability of death within 1 year after first stroke.

There is a striking relationship between the probability of mortality within the first year of the index of stroke and mortality. The relationship is seen irrespective of gender and race. (Redrawn with permission from Chapter 15 of [106])



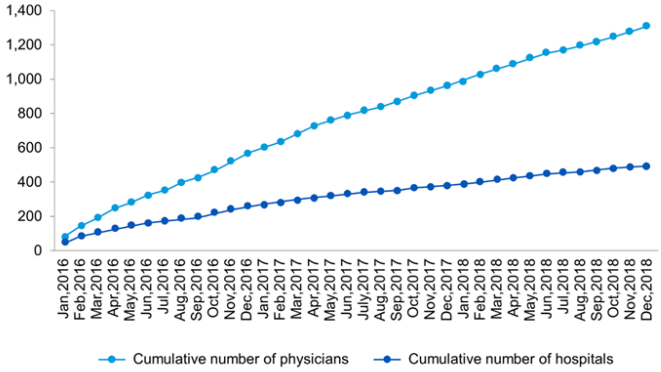
Supplementary Figure 3. Relative ischaemic stroke reductions compared with expected rates based on CHA_2DS_2-VASc scores.

For the two initial randomized clinical trials of Watchman 2.5 device, the FDA provided instructions for an accompanying registry (CAP) and (CAP2). These registries used the same criteria that had been used in the RCT's; they included up until that time the longest follow up of patients treated with Watchman 2.5. Because there was no randomization to study the outcome, a "control" group used outcome in patients in whom no treatment was given based on CHA_2DS_2-VASc. As seen, there was a marked improvement in the observed versus expected outcomes of ischemic stroke. (Reproduced with permission from [68])



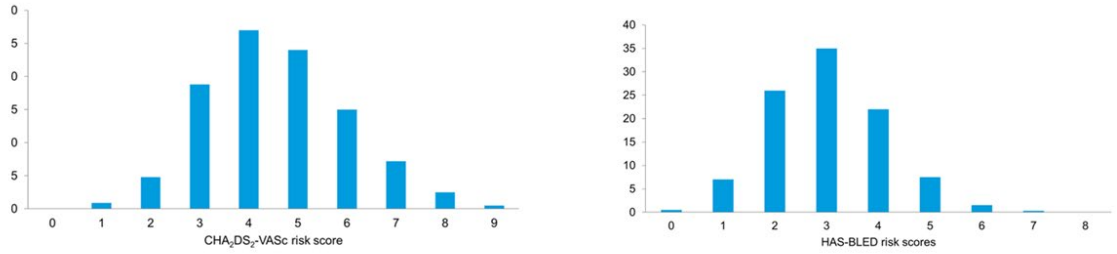
Supplementary Figure 4. FDA approval mandated a National Registry.

This LAAO Registry includes all consecutive patients treated with a commercial device. It documents a marked increase in procedural performance since device approval. (Reproduced with permission from [24])



Supplementary Figure 5. Increase in procedural volume by physicians and hospitals.

As documented in the National LAAO National registry, there has been not only a marked increase in procedural volume but also an increase in the number of physicians performing procedures as well as the number of hospitals. (Reproduced with permission from [24])



Supplementary Figure 6. Distribution of CHA_2DS_2-VASc and HAS-BLED scores among patients enrolled in the LAAO registry.

As seen, there is a wide baseline differences in patient risk characteristics evaluated by CHA_2DS_2-VASc and HAS-BLED score. (Reproduced with permission from [24])