A new preoperative approach based on 3Dprinted simulation in LAAC procedures data from "LAA-Print French registry": a large national multi-centric prospective registry (ClinicalTrials.gov ID: NCT03330210)

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Background:
LAAC are class IIb indication in patients with CI to OAC (2016 ESC Guidelines)
LAAC procedures may be at risk , especially in frail patients
Insurance French registry: FLAAC[1] raise awareness to serious complications
NNT=23 to avoid a thrombo-embolic event
NNH=14 to induce a serious event
There is no imaging criteria to asses individual procedural risk[2]
3D-printing simulation has capability to integrate all anatomical and procedural parameters
and has demonstrated improvements in LAAC device sizing in a pilot study[3]

Clinical aim: to predict the risk of procedural complications

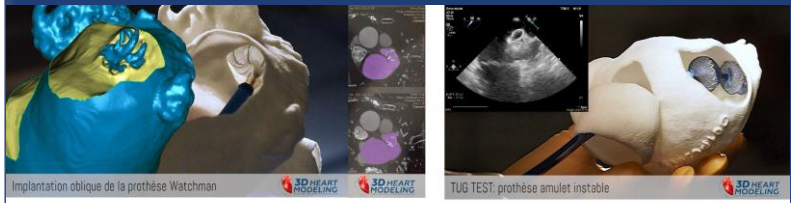
Methods:
Overall Status: recruiting (200patients in 16 centres)
Study Start: Jan 18th, 2018

1.Cardiac CT prior to LAAC Segmentation of left atrium
2.Industrial manufacture, laser sintering, of 3D-printed models including the whole LA cavity
3.LAAC Simulation based on 3Dprinted models using specific sheaths and prostheses (Watchman™ and Amulet®)
4.Verification of transseptal puncture site to avoid misalignment and sizing
5.Risk ranking for procedural failure (low/moderate/high) based on 3D printed LAAC simulation

[1]E Teiger, CircInterventions Volume: 11, Issue: 3
[2]C Fastner, EuroIntervention. 2018 Jun 20;14(2):176-184
[3]V Ciobotaru EuroIntervention. 2018 Mar 13.

Operative Risk Score based on 3D printing simulation observing 3 points: puncture site (postero-inferior or anterior), catheter alignment (good or misalignment) and prosthesis deployment (optimal or suboptimal or instable)

TOTAL OPERATIVE RISK SCORE is
Low : if the global additional Score if alignment device-LAA /no leak
Moderate risk: if the global score if misalignment or leak or bulging
High risk: if the global score if
(important catheter misalignment, instable device or ejected when tug test)



influence of transseptal puncture, on, device deployment
Posterior puncture Anterior puncture

Nb of patients N=200	Operative Predicted Low risk N=104	Operative Predicted Moderate risk N=59	Operative Predicted High Risk N=37
Failure	0	0	12 (32%)
Recaptures>2	3 (3%)	5 (10%)	7 (19%)
Prosthesis ≥2	1 (1%)	6 (2%)	8 (21%)
Inappropriate implantation	0	7 (10%)	11 (30%)
SAEs	0	5 (8%)	10 (27%)
Pericardial effusion>10mm Pericardiocentesis	4(4%) 1	3(5%) 2	4(11%) 2
Haemorrhage (≥2points)	0	2	8
Coronary syndrome	0	0	4
Time (intraLA) min	21±7	28±13	58±25

Factors associated with high risk group were: retroversion of the LAA, elliptical LAA ostium, marked flat chicken wing, shape, reduced depth

The operative risk score is the solely predictive parameter for occurrence of a primary end point (any serious adverse events or failed procedure or inappropriate implantation, or time>50min intra LA (logistic regression)

We propose a simple operative risk score based on 3D printing simulation observing 3 points: puncture site, catheter alignment and prosthesis deployment.
Our operative risk score, was validated prospectively and accurately stratifies the procedural risk: low, moderate or high
If high risk is pre-identified, a careful assessment of risk/benefice ratio is mandatory and specific tricks and adjustment of the procedure are paramount