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Feasibility, safety and clinical impact of a less-invasive totally-endovascular (LITE) technique for transfemoral TAVI: A 1000 patients single-centre experience

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ABSTRACT

Background: Trans-femoral (TF) represents the main access for TAVI. Although there are various technical strategies to conduct TF-TAVI (pacing modality, secondary arterial access, primary access puncture etc.), the optimal technique is not recognized.
Aims: In the present study, we assessed the impact of systematic use of LITE-TAVI in terms of feasibility, safety, and main access complication management using VARC-3 outcomes definitions.
Methods: At our institution, a less-invasive totally-endovascular (LITE) technique for TF-TAVI has been developed since 2017. Key aspects are: precise TAVI access puncture using angiographic-guidewire ultrasound guidance; radial/ulnar approach as the default "secondary access"; non-invasive pacing (by guidewire stimulation or definitive pacemaker external programmer).
Results: 1022 consecutive TF-TAVI patients (55 % women, mean age: 80 years, mean EuroSCORE II 6.1 %, mean STS-PROM 4.3 %, mean STS/ACC TVT TAVR mortality score 3.4 %) were approached using the LITE technique. Technical success was achieved in 993 (97.2 %) patients. Access-related major vascular complications occurred in 12 (1.2 %) and VARC-3 $\geq$ type 2 bleedings in 12 (1.2 %) patients. At 30-day, all-cause death occurred in 17 (1.7 %) patients. This figure resulted significantly lower than expected on the bases of the mortality predicted not only by EuroSCORE II (6.1 %, $p < 0.001$) and STS-PROM score (4.3 %; $p < 0.001$), but also by STS/ACC TVT TAVR mortality score (3.4 %; $p = 0.01$).
Conclusions: Systematic use of LITE-TAVI is feasible and is associated with an extremely low rate of access-related bleeding and vascular complications which may drive to outcome improvement.

1. Introduction

Bleeding and vascular complications (VC) represent a main concern for patients undergoing *trans*-femoral (TF) transcatheter aortic valve implantation (TAVI), as they are associated with an increase in morbidity and mortality [1–4]. With the indication for TAVI extending to younger and lower-risk patients [5,6], it is crucial to minimize these complications by adopting safer and easier percutaneous endovascular methods. Although there are various technical approaches for performing TF-TAVI, the optimal strategy has not yet been established.

Abbreviations: VC, Vascular Complication; TAVI, Transcatheter Aortic Valve Implantation; TF, Trans-femoral; LITE, Less-Invasive Totally-Endovascular; VC, Vascular Complications; PCI, Percutaneous Coronary Intervention; F, French; AGU, Angiographic-Guidewire Ultrasound; VCD, Vascular Closure Device; PTA, Percutaneous Transluminal Angioplasty; PM, Pacemaker; STS, Society of Thoracic Surgeons; VARC, Valve Academic Research Consortium; TAVR, Transcatheter Aortic Valve Replacement; CFA, Common Femoral Artery; SFA, Superficial Femoral Artery.

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Previously, an original combination of endovascular techniques for TF-TAVI, known as the "less-invasive totally endovascular" (LITE) technique, has been developed and preliminarily reported to be associated with promising results [7]. The aim of this study was to assess the safety and efficacy associated with the systematic use of LITE technique in a large cohort (>1000 patients) of TF-TAVI.

2. Methods

2.1. Study population

In this study, we examined the procedural and clinical data of all consecutive patients who underwent TF-TAVI at our Institution from January 2017 (when LITE-TAVI was introduced) through December 2023. According to the institutional clinical pathway for heart valve disease patients [8], patients were referred for TAVI after a formal multidisciplinary Heart Team discussion and underwent a comprehensive clinical, echocardiographic, and multislice computed tomography (MSCT) assessment following a standardized method [9]. Clinical data and procedure details were prospectively entered into a TAVI-dedicated section of an electronic database that allowed previously to assess the impact of European System for Cardiac Operative Risk Evaluator (EuroSCORE) on coronary interventions [10] and the safety of *trans*-radial procedures [11]. Patients' surgical risk was categorised according to the EuroSCORE II and the Society of Thoracic Surgeons (STS) predicted operative mortality (PROM) at the time of Heart Team consultation. TAVI risk was graded according to the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy using the on-line TAVI in-hospital mortality risk calculator (https://tools.acc.org/tavrrisk/#!/content/evaluate/). Since January 2017, we have adopted the LITE technique as the standard practice at our tertiary centre (Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy) for all patients eligible for TF-TAVI. Patients who could not undergo TF approach were excluded. This study complies with ethical guidelines of the 1975 Declaration of Helsinki and is part of an ongoing registry approved by our Ethics Committee (ID: 3940). All patients gave informed consent to the procedure.

2.2. LITE-TAVI technique description

LITE-TAVI technique (Video, Supplementary material) has been previously comprehensively described [7], and has three main key elements (**Graphical abstract**):

1) radial (or ulnar) approach as the default "secondary access" allowing to skip ancillary femoral artery access.
2) precise TAVI access puncture using angiographic-guidewire ultrasound (AGU) guidance.
3) non-invasive pacing (by guidewire stimulation or definitive pacemaker external programmer) allowing to skip systematic vein access.

Briefly, the *trans*-radial access (TRA) was selected as the default "secondary" access, primarily using the left radial artery and, if necessary due to unfavourable anatomy, the right radial artery (first alternative considered), or the (left or right) ulnar arteries (last alternatives considered in the case of unsuitable radial arteries). A combined ultrasound and angiographic guidance was used to facilitate the radial access selection and management [12].

In particular, real-time ultrasound ("echo-first" approach) was used to select the best vascular access and, together with angiography, to manage the potential obstacles that may occur during transradial procedures, as previously described [12]. A 6 Fr, 125 cm long multipurpose (MP) guiding catheter (GC) was then introduced through the radial/ulnar "secondary" access and advanced into the descending aorta over a 300-cm long, workhorse, 0.035" J-tip guidewire. Upon having engaged the selected iliac-femoral axis's iliac artery, TAVI femoral access was obtained using a previously described Angio-Guided-Ultrasound (AGU) technique [13]. The common femoral artery (CFA) was accessed through the best puncture site, identified by angiographic criteria (e.g., larger diameter and low/no calcium burden). A 0.035" J-tip guidewire was inserted into the CFA at this site, and ultrasound (US) was used to confirm the position of the guidewire and to guide the needle to the anterior wall of the artery, avoiding plaque or calcification. After accurate femoral puncture, a 9F femoral sheath was introduced; then the J-tip was withdrawn. In most cases, Perclose ProGlide™ or Prostyle™ (Abbott Vascular, Santa Clara, CA, USA) devices were used for a single or double pre-closure technique. After Perclose(S) deployment, the 9-F introducer was reinserted, and a 400 cm 0.018" guidewire (Plywire; Optimed, Norcross, GA, USA) was advanced through the MP catheter into the superficial femoral artery (SFA). Next, the MP catheter was removed and the 0.018" "protection" guidewire was left in the SFA to "secure" the main TAVI access [6]. After transfemoral, retrograde aortic valve crossing, a 0.035" stiff guidewire was used to exchange the 9-F sheath with the TAVI device introducer. Next, a 5 Fr pigtail catheter was inserted (along a 0.035" guidewire and aligned with the 0.018" "protection" guidewire) in the ascending aorta through the "secondary" radial/ulnar access, to guide in valve deployment. To avoid risks of central venous access and right heart catheterization, transvenous temporary pacemaker was not used routinely. In patients with permanent pacemaker, rapid pacing was achieved with the manufacturer's magnet-probe and external programmer. For all other patients, rapid and bail-out pacing was done through left ventricular stimulation with the stiff guidewire, using a crocodile electrode holder that connected the 0.035" wire to an external percutaneous pacing pad [6,13]. In the case of bradyarrhythmia development, the heart stimulation was transiently maintained by the non-invasive technique adopted (either external pacing or wire-based) while the "bail-out" venous access was taken (by US-guided femoral vein puncture) and a 6-F floating temporary pacemaker was used to definitively pace the right ventricle. TAVI implantation followed the manufacturer's guidelines and was performed using either self-expandable or balloon-expandable prostheses. After implantation, the TAVI sheath was removed, and haemostasis was achieved tightening the Perclose ProGlide™ or Prostyle™ (Abbott Vascular, Santa Clara, CA, USA) sutures. In some cases, especially for accesses ≥18-F or with specific anatomical features (brief subcutaneous tract, no calcium in the femoral artery), the plug-based MANTA™ (Teleflex, Morrisville, NC, USA) was used instead. The MP catheter was re-inserted through the "secondary" radial/ulnar access over the 0.018" "protection" guidewire to verify haemostasis and assess the condition of the iliac/femoral arteries. Moreover, the "secondary" radial access, as previously described [14,15], was used to manage persistent bleeding or VCs by delivering selected balloons, stents, or other devices (e.g., thrombectomy catheters) to achieve an "endovascular-first" approach to vascular complication management [16,17]. In the case of major blood leakage requiring self-expandable cover stents, transradial balloon inflation was used to block haemorrhage while the "bail-out" contralateral femoral access was taken (by US-guided puncture) and a 9F sheath was inserted and used for vascular complication management.

2.3. Study endpoints

The incidence of *peri*-procedural mortality, access-related major-VCs and ≥ type 2 bleedings constituted the primary endpoint of this study. All outcomes were defined according to the VARC-3 classification criteria [18]. Additionally, since the VARC-3 bleeding definitions were introduced in 2021 and has not undergone extensive clinical validation yet, we evaluated bleeding events using the VARC-2 definitions [19] as well, to make our data comparable to those reported in the landmark TAVI randomized trials.

Table 1
Baseline characteristics.

	Overall population (n = 1022)
Age (years)	80.5 ± 7.0
Female	564 (55.2)
BMI (kg/m^2)	26.5 ± 4.5
Cardiovascular risk factors	
Arterial hypertension	885 (86.6)
Dyslipidemia	663 (64.9)
Smoke history	369 (36.1)
Diabetes mellitus	294 (28.8)
Comorbidities	
Renal failure (eGFR < 60 ml/min/1.73 m^2)	344 (33.7)
Dialysis	19 (1.9)
COPD ≥ moderate	226 (22.1)
AF history	343 (33.6)
RBBB	40 (3.9)
PMK holder before TAVI	148 (14.5)
PAD	225 (22.0)
Prior stroke	82 (8.0)
Prior ACS	131 (12
Prior PCI	270 (26.4)
Prior CABG	78 (7.6)
Prior cardiac non coronary surgery	89 (8.7)
Clinical presentation	
NYHA functional class III-IV	597 (58.4)
Risk scores	
EuroScore II (%)	6.3 ± 7.1
STS/ACC TVT TAVR mortality score (%)	3.4 ± 2.5
STS-PROM (%)	4.3 ± 2.7
Low surgical risk (PROM < 4)	585 (57.2)
Intermediate surgical risk (PROM 4–8)	327 (32.0)
High surgical risk (PROM > 8)	110 (10.8)
Echocardiographic data	
LVEF (%)	55.5 ± 11.7
Mean gradient (mmHg)	48.6 ± 16.1
AVA-D (cm^2)	0.74 ± 0.24
AR (≥ moderate)	116 (11.4)

Values are N (%) or mean ± SD.
Abbreviations: BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; AF: Atrial Fibrillation; RBBB: right bundle branch block; PMK: Pacemaker; PAD: Peripheral Artery Disease; ACS: Acute Coronary Syndrome; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft; NYHA: New York Heart Association; TAVR: Transcatheter Aortic Valve Replacement; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; LVEF: Left Ventricular Ejection Fraction; AVA-D: Aortic Valve Area-Doppler; AR: Aortic Regurgitation

2.4. Statistical analysis

Continuous variables were presented as mean ± SD, and categorical variables as counts and proportions. Observed deaths were compared with expected deaths as estimated by EuroSCORE II, STS-PROM score and STS/ACC TVT TAVR mortality score using a χ^2 test. A 2-tailed p value <0.05 was established as the level of statistical significance. All data analyses were done using SPSS version 29.0 (IBM Corp, Armonk, NY, USA).

3. Results

3.1. Baseline and patient characteristics

From January 2017 to December 2023, our Institution referred 1106 patients for TAVI. Out of these, in 1022 patients (92.4 %) the procedure was performed via TF access. These patients constituted the intention-to-treat study population. The remaining 84 patients (7.6 %) were treated through alternative access routes: *trans*-carotid (2 patients, 0.2 %), *trans*-subclavian (13 patients, 1.2 %), *trans*-aortic (2 patients, 0.2 %), and *trans*-apical (67 patients, 6.0 %). Patient' demographics and baseline characteristics are detailed in Table 1. The mean age was 80.5 ± 7.0 years, with females constituting 55.2 % of the population. Prevalent comorbidities included arterial hypertension (885 patients, 86.6 %), diabetes mellitus (294 patients, 28.8 %), and renal failure (344 patients, 33.7 %). Risk assessment scores showed a mean STS-PROM of 4.3 ± 2.7 % and a mean STS/ACC TVT TAVR mortality score of 3.4 ± 2.5 %. Based on the STS-PROM, 327 patients (32.0 %) had intermediate surgical risk, while 110 patients (10.8 %) were categorized as high-risk.

Table 2
Procedural characteristics.

	Overall population (n = 1022)
TAVI status	
Elective	848 (83.0)
Urgent/emergent	174 (17.0)
Main arterial access site	
Right femoral	715 (70.0)
Left femoral	307 (30.0)
Secondary access site	
Radial artery	970 (94.9)
Ulnar artery	41 (4.0)
Contralateral femoral	11 (1.1)
Secondary access switch	
Switch from radial/ulnar to contralateral radial/ulnar	16 (1.6)
Switch from radial/ulnar to femoral artery	1 (0.1)
Third arterial access (for additional interventions)	
Contralateral radial/ulnar	39 (3.8)
Contralateral femoral	18 (1.8)
Valve sheath size	
14 Fr	379 (37.1)
>14 Fr	643 (62.9)
Procedural data	
Valve in valve TAVI	55 (5.4)
Self-expandable valve	816 (79.8)
Prosthesis size, mm	27.3 ± 3.0
Pre-dilation	650 (63.6)
Post-dilation	174 (17.0)
Cerebral protection	12 (1.2)
Coronary protection	50 (4.9)
Total contrast media dose, mL	293.1 ± 92.6
Total fluoroscopy time, min	27.9 ± 10.9
Technical success	993 (97.2)
Cardiac pacing modality	
Left ventricle pacing through stiff guidewire	878 (85.9)
Permanent PM external programmer	136 (13.3)
Temporary PM at the procedure' start	8 (0.8)
Shift from guidewire pacing to temporary PM	73 (7.1)
Guidewire pacing failure	6 (0.6)
Temporary PM due to significant bradyarrhythmia	67 (6.6)
Pre-TAVI peripheral PTA	37 (3.6)
Radial access	8 (0.4)
Femoral anterograde contralateral access	1 (0.1)
Femoral retrograde access	28 (2.7)
Cardiac and non-cardiac structural complications	
Valve malposition	16 (1.6)
Post-TAVI coronary obstruction	7 (0.7)
Acute pericardial effusion/cardiac tamponade	11 (1.1)
Need for snaring	8 (0.8)
Valve in valve (same procedure)	8 (0.8)
Emergency conversion to open heart surgery	4 (0.4)

Values are N (%) or mean ± SD.
Abbreviations: TAVI: Transcatheter Aortic Valve Implantation; Fr: French; PTA: Peripheral Transluminal Angioplasty; VCD: Vascular Closure Device.

3.2. Procedural characteristics

Table 2 shows the procedural data. Briefly, most of the TAVI procedures had an elective status (848, 83.0 %), while the rest were urgent or emergent (174, 17.0 %). The main indication for TAVR was native aortic valve disease (967 cases, 94.6 %), while in 55 cases (5.4 %) a valve in valve procedure was performed. Overall, the technical success was obtained in 993 cases (97.2 %). Fig. 1 shows the study population (1022 patients) that underwent TF-TAVI with the LITE technique. In 22 cases the standard LITE-TAVI protocol was not followed and a

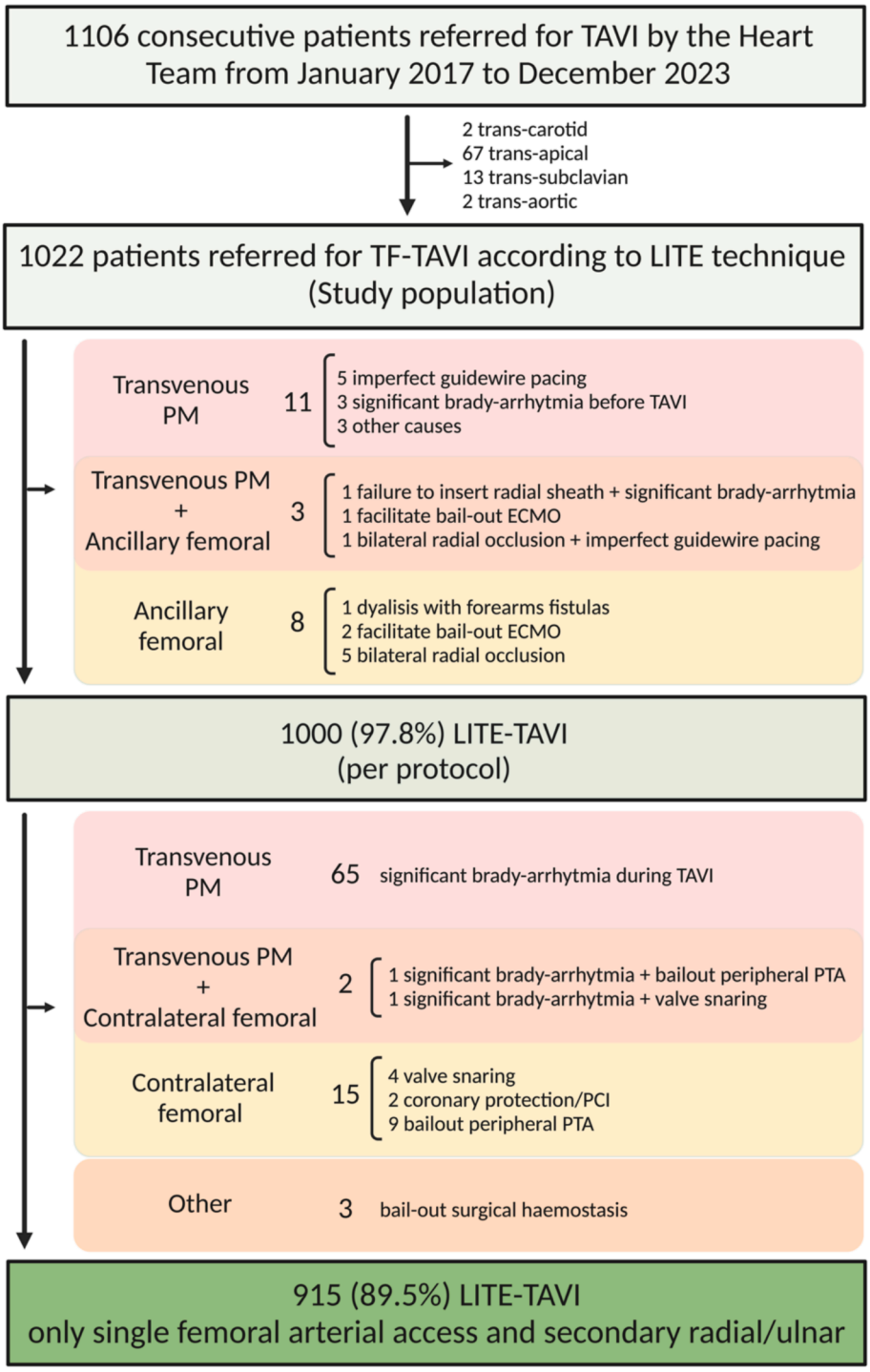

Fig. 1. Study selection algorithm. *Abbreviations. TAVI = transcatheter aortic valve implantation; TF = trans-femoral; LITE = Less-Invasive Totally-Endovascular; PM = pacemaker.*

contralateral arterial femoral access and/or invasive pacing was considered to be electively required from procedure beginning due to anatomical limitations (e.g., bilateral radial artery occlusion), inability to pace through the stiff guidewire, or other clinical situations (urgent procedures where it might need a bail-out extracorporeal membrane oxygenator [ECMO]. Therefore, in 97.8 % of cases (1000 out of 1022), the LITE-TAVI protocol was adopted. During TF-TAVI, 65 patients (6.4 %) needed transvenous temporary pacing due to severe bradyarrhythmia, and 15 patients (1.5 %) needed contralateral femoral arterial access for additional interventions such as peripheral PTA, valve snaring, or coronary protection. In 2 cases (0.2 %), invasive pacing and a contralateral arterial femoral access were both required.

3.3. Vascular complications and their endovascular management

The details of VCs and their endovascular management are shown in Table 3. According to VARC-3 criteria [18], out of 1022 patients, 129 (12.6 %) experienced access-related VCs, major in 12 (1.2 %) and minor in 117 (11.5 %) cases. Out of minor-VCs, 91 (8.9 %) occurred at the main femoral access site, while 26 (2.5 %) occurred at the "secondary" radial/

Table 3
30-day vascular complication and management, bleedings, and clinical outcomes according to VARC-3 criteria.

	Overall population (n = 1022)
Overall vascular complication	136 (13.3)
Minor vascular complications	122 (11.9)
Major vascular complications	14 (13.7)
Access site vascular complication	129 (12.6)
Minor vascular complication	117 (11.4)
Major vascular complication	12 (1.2)
Primary access site vascular complication	103 (10.1)
Minor vascular complication	91 (8.9)
Major vascular complication	12 (1.2)
Secondary access site vascular complication	26 (2.5)
Radial/ulnar artery minor vascular complication	26 (2.5)
Radial/ulnar artery major vascular complication	0
Access-related non-vascular complication	2 (0.2)
Minor vascular complication	2 (0.2)
Major vascular complication	0
Bail-out endovascular treatment of vascular complication	
Procedures that required peripheral intervention	108 (10.6)
Only balloon-hemostasis	39 (3.8)
PTA (not hemostasis)	55 (5.4)
Balloon hemostasis + PTA	14 (1.4)
Need for bail-out non-covered stent implantation	7 (0.7)
Need for bail-out covered stent implantation	9 (0.9)
Vascular access used for peripheral intervention	
Only radial/ulnar access	92 (85.2)
Retrograde ipsilateral femoral access	1 (0.9)
Contralateral femoral access	14 (13.0)
Bail-out surgery	1 (0.1)
Bleeding	
Type 1	118 (11.5)
Type 2	64 (6.3)
Type 3	12 (1.2)
Type 4	5 (0.5)
Access-related bleeding complications	
Type 2	4 (0.4)
Type 3	7 (0.7)
Type 4	1 (0.1)
Post-TAVI hospitalization length, days	6.3 ± 5.8
30-day clinical outcomes	
All cause death	17 (1.7)
Stroke	27 (2.6)
Need for permanent pacemaker	180 (17.6)

Values are N (%) or mean ± SD.
Abbreviations: PTA: Percutaneous Transluminal Angioplasty; VARC: Valve Academy Research Consortium; TAVI: Transcatheter Aortic Valve Implantation.

ulnar access site. As shown in Table 3, **108** (10.6 %) procedures required endovascular peripheral intervention. Of these, 39 (3.8 %) only needed balloon-haemostasis, 55 (5.4 %) required PTA, 14 (1.4 %) needed both balloon-haemostasis and PTA and 9 (0.9 %) required covered stent implantation. To adequately perform the previously described peripheral interventions, in 92 (85.2 %) cases the "secondary" radial/ulnar access was sufficient. In 1 (0.9 %) case, a retrograde ipsilateral femoral access was needed, while in 14 (13.0 %) cases a contralateral arterial femoral access was used. Out of the 14 cases that required contralateral arterial femoral access, only 10 were due to the inadequacy of radial/ulnar access. The remaining 4 cases were performed from the procedure' beginning through ancillary femoral access and did not constitute the LITE-TAVI protocol population (Fig. 2). If a VC occurred at the ancillary access, such as acute thrombosis or dissection, it was treated using a retrograde approach with thrombo-aspiration devices and/or balloons in all cases.

3.4. Bleedings and clinical outcomes

Regarding bleeding complications, type 1 (VARC-3) occurred in 118 (11.5 %) patients, type 2 (VARC-3) in 64 (6.3 %) patients, type 3 (VARC-3) in 12 (1.2 %) patients, and type 4 (VARC-3) in 5 (0.5 %) patients, as shown in Table 3. Of note, bleeding complications related to the access-site were extremely rare, with type 2 (VARC-3) occurring in 4 (0.4 %) patients, type 3 (VARC-3) in 7 (0.7 %) patients and type 4 (VARC-3) in 1 (0.1 %) patient.

At 30-day follow-up, 17 (1.7 %) died, 27 (2.6 %) had a stroke, and 180 (17.6 %) required a permanent pacemaker.

Overall, as shown in Fig. 2, the observed death rate (1.7 %) was significantly lower than that expected based on the mortality predicted by the two surgical scores (EuroSCORE II: 6.1 %, $p < 0.001$; STS-PROM score: 4.3 %; $p < 0.001$) and by the STS/ACC TVT TAVR mortality score (3.4 %; $p = 0.01$).

4. Discussion

TF access is the most used and safe TAVI access route compared to non-femoral accesses [20]. However, there is no consensus on the best technical approach for performing TF-TAVI, as different strategies exist. In this paper we reported the results of the systematic adoption of a previously described [7] original combination of technical strategies that result in a less invasive (lower number of vascular accesses) and fully endovascular (for both access insertion and vascular complications management) TF-TAVR. The reported results show that the systematic LITE technique use in patients undergoing TF-TAVI is associated with.

- High feasibility
- A very low rate of serious bleedings and major-VCs (which we promptly detected and managed)
- A low mortality rate that compares favourably with predicted surgical and TAVI risk scores.

Within the limitations of a single-centre observational study, these findings support the concepts that technical refinements aimed at reducing the occurrence and the clinical sequelae of vascular complications might optimize the clinical outcome and call for a standardization of the TF-TAVI technique.

4.1. The pivotal role of a precise femoral artery puncture

Effective bleeding and VC prevention starts with thorough pre-procedural planning and precise vascular puncture [7]; targeting a non-calcified, healthy point is crucial for the effective deployment of vascular closure devices (VCD). Furthermore, avoiding the CFA bifurcation is crucial for safely managing bleeding and VCs, particularly when a peripheral covered stent is needed. US guidance is increasingly recognized for enhancing the safety and precision of arterial puncture. A recent sub-analysis of the UNIVERSAL (Routine Ultrasound Guidance for Vascular Access for Cardiac Procedures) trial [21] and a *meta*-analysis [22] revealed that, in procedures where a VCD is used, those who underwent US-guided femoral access experienced fewer bleeding and VCs compared to those who did not. While US-guidance offers many benefits, it's not without limitations; particularly, in high CFA bifurcations, this technique may lead to a higher vascular puncture. To reduce the risk of a sub-optimal CFA puncture the Angio-Guided-Ultrasound (AGU) technique [13], which combines the benefits of US-guided femoral artery puncture with fluoroscopy, was used in all patients of our cohort. In our study, the selection of an optimal puncture site through pre-procedural MSCT planning and intra-procedural combined angiographic and US assessment with the AGU technique enabled effective haemostasis using VCDs in most cases. Peripheral interventions for bleeding management were infrequent; balloon-assisted haemostasis was performed in 53 (5.2 %) of cases while bail-out covered stent implantation was needed in 9 (0.9 %) of cases.

4.2. Selecting the minimally invasive strategy during TAVI

During percutaneous procedures, any additional access carries

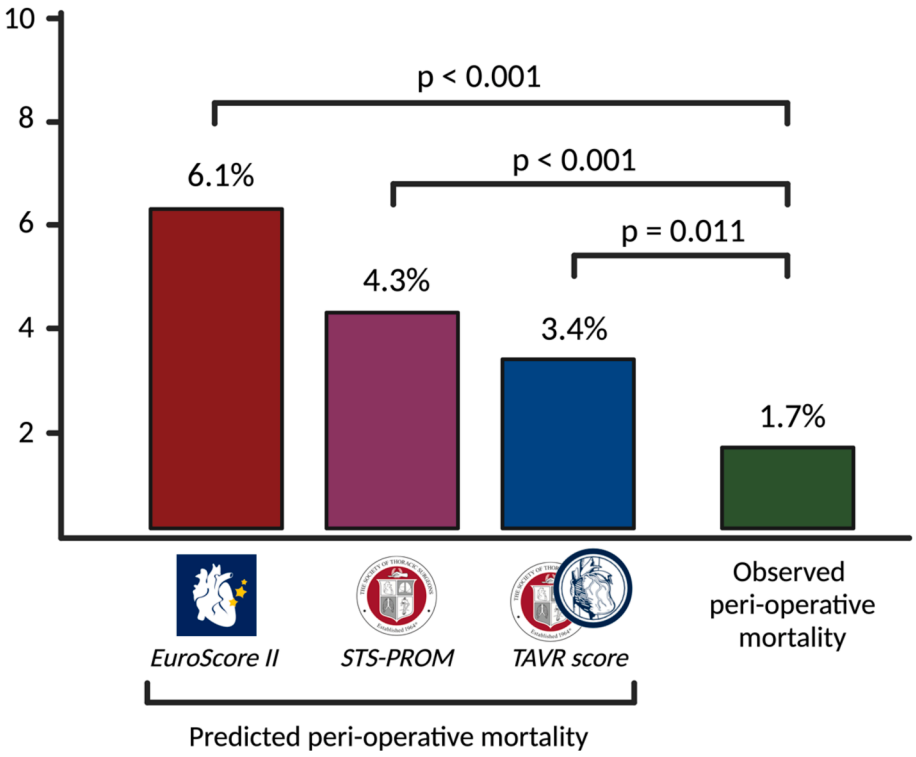

Fig. 2. Observed and predicted mortality in the LITE-TAVI study population.

further risks. Some studies show as about 25 % of TAVI VCs are due to TF secondary access [23,24]. These complications can be avoided and applying what we have learned from percutaneous coronary intervention (PCI) to TAVI seems relevant [25]; in the coronary setting, switching from the femoral to the radial access has been the most effective way to reduce bleeding and mortality [26]. Similarly, the use of "secondary" radial access during TAVI has been demonstrated to be associated with a significant reduction in vascular and bleeding complications and improved 30-day outcomes [3,23,24,27]. However, even with these positive results, many centres did not adopt the "secondary" radial approach as their standard routine practice [7]. The main disadvantages of using the radial artery as a "secondary" access route for TAVI are the challenges of handling different anatomical variations in the upper arm [28] and the potential limitations in managing primary TF access complications[15]. Such issues prompted us to adapt a specific radial approach technique to the specific context of TAVI [12]. To minimize the impact of adverse anatomic variants, the following measures were adopted [7]: routine examination of epi-aortic vessels anatomy using pre-procedure MSCT scanning and/or coronary angiography (when accessible); preference for the left radial artery, which is associated with fewer vasculature abnormalities, especially in patients ≥80 years old [29]; and use of the ulnar artery when bilateral abnormal radial anatomy was known or suspected (by pre-operative US assessment) [7]. This comprehensive approach allowed us to successfully use "secondary" radial/ulnar access in 1011 of 1022 TF-TAVI procedures (98.9 %) (Fig. 2). Regarding the safety of the "secondary" access, our cohort data revealed that among 129 reported VARC-3 access-related VCs, 26 (20.2 %) occurred at the radial/ulnar site. All these were minor-VCs and did not require further interventions, with 21 cases consisting in radial/ulnar artery occlusion post-TAVI.

Moreover, in this study we demonstrated the effectiveness of "secondary" radial/ulnar access in addressing potential issues with haemostasis and VCs of femoral TAVI access. Out of the 108 cases (10.6 %) requiring peripheral intervention (e.g. balloon haemostasis and/or PTA), radial/ulnar access proved sufficient in 92 (85.2 %) cases. Conversely, 14 out of 108 cases required an additional contralateral femoral access. This was needed mainly to accommodate the use of larger-sized balloons and covered stents, which are incompatible with 6- or 7-French systems. These findings reinforce the feasibility and efficacy of *trans*-radial access in managing most peripheral vascular complications.

Another aspect of the LITE-TAVI technique is the routine use of non-invasive pacing; this strategy is aimed at reducing the risks associated with additional vascular access, which can include bleeding and accidental arterial puncture. This approach also aids in preventing complications related to the insertion of a temporary pacemaker, such as pericardial effusion. A comprehensive, multi-centric study [30] involving over 360,000 patients revealed that temporary pacemaker is generally safe but is not free from complications: pericardial tamponade occurred in 0.6 % of the cases, pneumothorax in 0.9 %, and non-pericardial bleeding was observed in 2.4 % of the patients. In our study, the adoption of non-invasive pacing (by guidewire stimulation or definitive pacemaker external programmer) allowed us to avoid the use of a temporary pacemaker in 92.1 % of cases. In addition, in our cohort only 6 cases (0.6 %) needed pericardiocentesis to treat acute pericardial effusion. Out of the 40 (3.9 %) patients with prior complete right bundle branch block (RBBB), thus at high risk to develop conduction disturbances after TAVI, 17 (1.6 %) patients required temporary pacing during the procedure, with 12 (1.2 %) patients needing it at the end. All patients were closely monitored with electrocardiographic monitoring for 24–48 h after TAVI. Among those with prior RBBB, 12 (1.2 %) needed an in-hospital pacemaker.

4.3. *Safety and clinical impact of the LITE-TAVI technique*

In this study, the LITE-TAVI technique was shown to be feasible and to have a very low rate of bleeding and VCs. In 915 patients (89.5 %), TF-TAVI was performed without requiring an additional femoral (arterial and/or venous) access, fulfilling the LITE protocol; considering that in 76 cases (7.6 %) a temporary PM was needed at the beginning or during the procedure, 991 cases (96.9 %) were performed without requiring access to the contralateral femoral artery. These factors, together with

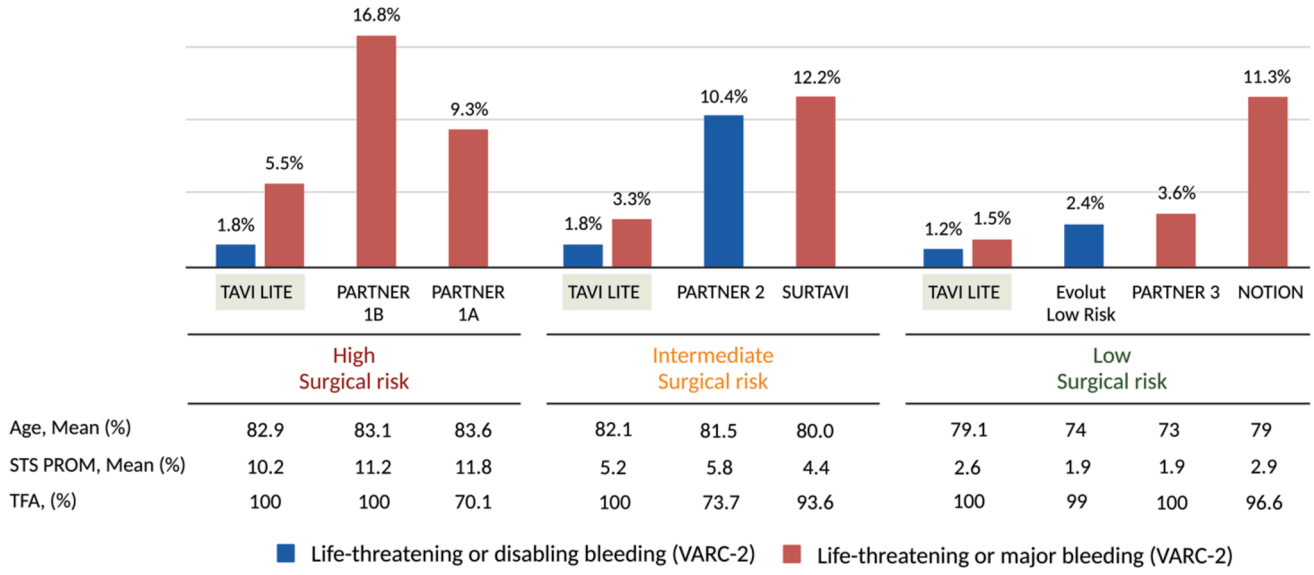

Fig. 3. VARC-2 bleeding in TAVI-LITE cohort compared with pivotal clinical trials according to surgical risk.

the use of an accurate femoral puncture method (the AGU technique), could account for the very low rate of access-related major-VCs (1.2 %) that we observed in our LITE-TAVI cohort. Recently, the MultiCLOSE algorithm [31], a protocol for managing large-bore arterial access in TF-TAVI, has been described, showing rate of major-VCs below 1 % (0.6 %). Notably, the MultiCLOSE study excluded patients with severe peripheral arterial disease undergoing TF-TAVI, who were treated with intravascular lithotripsy-assisted TF-TAVI. However, the study did encompass 95–100 % of all other consecutively treated TF-TAVI patients where the MultiCLOSE vascular closure algorithm was applied [31]. In contrast, our study encompassed all consecutive TF-TAVI candidates, regardless of the peripheral artery condition, the need for pre-TAVI PTA or the feasibility of using the LITE-TAVI technique.

In our cohort we observed a low rate of significant bleeding; VARC-3 type 2 (64, 6.3 %), type 3 (12, 1.2 %) and type 4 (5, 0.5 %). Remarkably, very few access-related bleedings occurred, as well as type 2 (4, 0.4 %), type 3 (7, 0.7 %) and type 4 (1, 0.1 %). Considering that the VARC-3 bleeding definitions were introduced in 2021 and has not undergone extensive clinical validation, we evaluated bleeding events using the VARC-2 definitions [19] as well, to make our data comparable to those reported in the landmark TAVI randomized trials, as shown in Fig. 3. When compared to these studies, our LITE-TAVR cohort experienced less bleedings, and these data were consistent across the different surgical risk categories.

Therefore, in our cohort, the notable decrease in vascular complications and subsequent bleedings may have significantly reduced mortality rates, both in-hospital (1.6 %) and at 30 days (1.7 %). Remarkably, our observed mortality rates were substantially lower than those predicted by STS/ACC TVT TAVR mortality score (1.6 % vs. 3.4 %, $p = 0.007$) and STS-PROM scores (1.7 % vs. 4.3 %, $p < 0.001$).

4.4. Limitations

The data presented have been collected in the setting of a single-centre, observational study where a limited number of operators both contributed to develop and to practice the technique. This particularly relevant since the interventional cardiology centre has a long-lasting experience in the systematic adoption for transradial approach for both routine [11] and complex coronary interventions [32–34] and pioneered the use of transradial approach for peripheral interventions [15,35–39] thus creating a unique environment. In addition, it was not possible to assess the individual impact of the three main techniques (radial access, non-invasive pacing, and AGU technique) as they were all implemented simultaneously. Furthermore, the LITE-TAVI method for TF-TAVI has been implemented in a high-volume tertiary center with high-expertise. Therefore, these results should also be confirmed in centers with lower expertise. Accordingly, the feasibility data reported in the study need to be confirmed in other experiences and the true clinical benefit deserves a prospective randomized trial to be assessed.

5. Conclusions

Systematic use of LITE-TAVI is feasible and is associated with an extremely low rate of access-related vascular and bleeding complications which may drive to outcome improvement. Within the limitation of a single-centre experience, the present study calls for a standardization of the technique for TF-TAVI.

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CRediT authorship contribution statement

Enrico Romagnoli: Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Francesco Bianchini:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Cristina Aurigemma:** Writing – review & editing, Investigation. **Andrea Zito:** Writing – review & editing, Formal analysis. **Emiliano Bianchini:** Writing – review & editing, Data curation. **Lazzaro Paraggio:** Writing – review & editing, Formal analysis, Data curation. **Mattia Lunardi:** Writing – review & editing, Data curation. **Carolina Ierardi:** Writing – review & editing. **Marialisa Nesta:** Writing – review & editing, Data curation. **Piergiorgio Bruno:** Writing – review & editing, Data curation, Conceptualization. **Francesco Burzotta:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Carlo Trani:** Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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BioRender platform and templates were used for creating figures and graphical abstract.

Appendix A. Supplementary material

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