Minimally invasive surgical versus transcatheter aortic valve replacement: A multicenter study

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ABSTRACT

Objectives: Treatment of aortic valve stenosis is evolving, indications for transcatheter approach (TAVI) have increased but also surgical valve replacement has changed with the use of minimally invasive approaches. Comparisons between TAVI and surgery have rarely been done with minimally invasive techniques (mini-SAVR) in the surgical arm. Aim of the present study is to compare mini-SAVR and TAVI in a multicenter recent cohort.

Methods: Evaluated were 2904 patients undergone mini-SAVR (2407) or TAVI (497) in 10 different centers in the period 2011–2016. The Heart Team approved treatment for complex cases. The primary outcome is the incidence of 30-day mortality following mini-SAVR and TAVI. Secondary outcomes are the occurrence of major complications following both procedures. Propensity matched comparisons was performed based on multivariable logistic regression model.

Results: In the overall population TAVI patients had increased surgical risk (median EuroSCORE II 3.3% vs. 1.7%, p ≤ 0.001) and 30-day mortality was higher (1.5% and 2.8% in mini-SAVR and TAVI respectively, p = 0.048). Propensity score identified 386 patients per group with similar baseline profile (median EuroSCORE II ~3.0%). There was no difference in 30-day mortality (3.4% in mini-SAVR and 2.3% in TAVI; p = 0.396) and stroke, surgical patients had more blood transfusion, kidney dysfunction and required longer ICU and hospital length of stay while TAVI patients had more permanent pace maker insertion.

Conclusions: Mini-SAVR and TAVI are both safe and effective to treat aortic stenosis in elderly patients with comorbidities. A joint evaluation by the heart-team is essential to direct patients to the proper approach.

1. Introduction

Treatment of aortic valve stenosis is rapidly evolving. The advent of transcatheter aortic valve implantation (TAVI) has been a milestone in the treatment of this pathology [1] and for the diffusion of new transcatheter based cardiac interventions. The development of new and more reliable prosthesis and catheters has reduced the incidence of

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vascular complications and paravalvular leaks [2,3] and the indications for transcatheter based approach has dramatically increased [4].

Surgical aortic valve replacement (SAVR) has also progressed: cardiopulmonary bypass (CPB) induced complications have been attenuated; anesthesia protocols allows faster recovery [5]; surgery is often performed with minimally invasive access. The knowledge regarding the most alarming and deadly complications (i.e. acute kidney injury, stroke, excessive bleeding) has increased, thus assuring better postoperative results. The European guidelines suggests that in patients who are at increased surgical risk the decision between SAVR and TAVI should be made by the Heart Team according to individual patient characteristics [4]. Excluding meaningless competition between medical actors from the decision-making can be essential to produce excellent clinical outcome.

When SAVR is the preferred strategy, minimally invasive techniques (mini-SAVR) produce better clinical outcome than standard full sternotomy approach [6,7]: patients experience less postoperative bleeding, shorter mechanical ventilation time and shorter ICU and hospital length of stay with increased satisfaction and psychological acceptance [8]. The evaluation of the results obtained with SAVR or TAVI has rarely included minimally invasive approach in the surgical arm.

The aim of the present study is to report results obtained with mini-SAVR and TAVI in a multicenter recent cohort in which the Heart Team approach has been widely adopted.

2. Methods

Data from 10 Italian cardiac centers belonging to the same company (GVM Care & Research) were analyzed. In all centers cardiology and cardiac surgery divisions are unified in a single department sharing the same clinical and administrative organization. The Heart Team concept has been widely adopted to consider comorbidities, surgical risk and technical feasibility of transcatheter procedures.

All patients who received SAVR through a minimally invasive approach (partial hemi-sternotomy or right anterior mini-thoracotomy) and all patients treated with TAVI were considered for the analysis. No exclusion criteria were applied.

Clinical and administrative databases are prospectively utilized in all centers. All patients sign an informed consent form to allow clinical and administrative data storage and utilization for scientific purposes. Because of the retrospective nature of this study, the local Ethics Committees waived the need for patient consent.

Missing data in the overall population: BMI 477 (16.4%), hypertension 55 (1.9%), diabetes 57 (2.0%), hypercholesterolemia 55 (1.9%), renal dysfunction 155 (5.3%), lung disease 106 (3.7%), neurological dysfunction 55 (1.9%), cancer 155 (5.3%), atrial fibrillation 155 (5.3%), peripheral vascular disease 55 (1.9%), coronary artery disease 62 (2.1%), previous cardiac surgery 50 (1.7%), and left ventricular ejection fraction 79 (2.7%); blood transfusion 133 (4.6%), renal function worsening 132 (4.5%), atrial fibrillation 392 (13.5%, including patients in preoperative atrial fibrillation), wound infection 7 (0.2%), reopening bleeding/complications 140 (4.8%), re-intubation 232 (8%), confusion/delirium 139 (4.8%), transient ischaemic attack or stroke 139 (4.8%), IAPB or Inotropic Agents in 100 (3.4%), and ICU and hospital length of stay in 151 (5.2%).

Study Design: retrospective evaluation of prospectively collected data during the period January 2011–December 2016.

The primary outcome of the study is the comparison of the incidence of 30-day mortality following mini-SAVR and TAVI. For discharged patients, the follow-up was performed at internal outpatient clinics or at referral centers. Secondary outcomes are the occurrence of major complications following both procedures: stroke, kidney function worsening, permanent pacemaker insertion, reopening for bleeding, vascular access site complications, low cardiac output. All major outcomes have been reported according to VARC-2 definitions [9].

The choice of performing a minimally invasive approach and the type of minimally invasive approach was based on surgeons' preference. The mini-sternotomy is performed in a J-shaped fashion, up to the third/fourth intercostal space. Both arterial and venous cannulation are carried out centrally through the main surgical site (ascending aorta and right atrium with a double-stage cannula). If difficult exposure of the right atrium is encountered, venous drainage is achieved with percutaneous venous cannulas, advanced through the right femoral vein into the right atrium. Accurate positioning is achieved using the Seldinger technique under transoesophageal echocardiographic guidance. The right anterior mini-thoracotomy is performed through a 5–7 cm incision usually at the level of the second intercostal space, although some surgeons prefer the third intercostal space. No rib resection is performed. The choice between ascending aorta or femoral arterial cannulation depends on anatomy and the surgeon's preference. Venous drainage is achieved in the fashion described for mini-sternotomy. A preoperative computed tomography (CT) scan without contrast enhancement is obtained to evaluate the anatomical relationship between the intercostal spaces, sternum, ascending aorta and aortic valve. Vacuum-assisted cardiopulmonary bypass is established, a left ventricular vent is placed through the right superior pulmonary vein or the pulmonary artery, and the patient is cooled to 34 °C. The ascending aorta is clamped with the external cross-clamp and anterograde cardioplegic solution is given into the aortic root or selectively into the coronary ostia using warm blood cardioplegia or cold crystalloid solution. In all cases, the surgical field is flooded with carbon dioxide at a flow of 0.5 l/min. In all cases, standard stented aortic valve prostheses have been implanted (mechanical prostheses: CarboMedics and Bicarbon aortic valves families, CarboMedics/LivaNova, London, United Kingdom; biological prostheses: porcine Hancock II and Mosaic™, Medtronic, Minneapolis, MN; pericardial: Carpentier-Edwards, Edwards Lifesciences, Irvine, CA, Mitroflow and Crown PRT LivaNova/Sorin, London, United Kingdom); no sutureless or rapid deployment valves have been utilized. In the same period, 2599 patients underwent SAVR in the same centers through a full sternotomy.

Patients planned for TAVI receive full preoperative evaluation; including lung functional test, transthoracic and transoesophageal echocardiography, enhanced computed tomographic scanning for an accurate assessment of the aortic annulus, aorta and peripheral vessels for the selection of the TAVI procedure. Most of the trans-catheter procedures were performed through trans-femoral approach (n = 486; 98%). Old and new generation self-expanding valves and mechanical expanding valves have been employed in all cases: Medtronic CoreValve® system, Medtronic Inc., Minneapolis, Minnesota (n = 453); Lotus™ valve system, Boston Scientific, MA, USA (N = 33). Initially all trans-femoral implants required general anesthesia and transoesophageal echocardiographic guidance, more recently most of them are performed in light sedation. The transapical approach (11 patients) was performed through a small intercostal incision over the left ventricular apex. Rapid ventricular pacing was utilized only in mechanical expanding valves. Immediately after TAVI, aortography was performed to assess the location and degree of aortic regurgitation and patency of the coronary arteries. Paravalvular leak more than mild were corrected with post-dilatation.

Patients in both groups underwent clinical assessment and transthoracic echocardiogram at hospital discharge.

2.1. Statistical analysis

Data are reported as mean and standard deviation, median (interquartile range) or percentage for categorical variables. We used the Student's t-test to compare continuous variables. Associations between categorical variables were evaluated by using Chi-squared test or Fisher test as appropriate. Since many pre-operative variables were different between SVR and TAVI groups, we evaluated a propensity score-matched cohort by using an automated procedure to pair patients 1:1

from SVR and TAVI procedures. The propensity score was based on multivariable logistic regression model including pre-operative variables. In this model, categorical data were analyzed with a missing indicator variable (BMI in three groups ≤25, 26–30, and >30 Kg/m^2; left ventricular function in three groups >50%, 31–50%, or ≤30%). The model had good discrimination and calibration in predict TAVI procedure (c-statistic = 0.874 and Hosmer-Lemeshow test p = 0.180). Matching was performed in a 1:1 ratio using a caliper width of 0.25 of the standard deviation of the linear predictor of the estimated propensity score [10]. The success of matching was evaluated by computing absolute standardized differences in the distribution of patient characteristics in the matched cohort before and after matching. Post-matching standardized differences <10% indicate successful balance (Fig. 1). A conditional logistic regression model, appropriate for matched data, was used to compare data of paired patients. No correction for multiple testing was performed. All the statistical tests were two-sided and p values of 0.05 or less were considered statistically significant. All analyses were conducted using STATA software, version 14 (Stata-Corp LP, College Station, Tex).

3. Results

During the study period, 2904 patients were eligible for this study: 2407 had mini-SAVR (1522 patients received an upper-mini-sternotomy, 855 patients were operated through right mini-thoracotomy) and 497 had TAVI (Table 1). In the global population patients receiving transcatheter interventions had increased surgical risk (Table 1) with EuroSCORE II significantly higher in TAVI patients: median 3.3% ((2.3–6.0) vs 1.7% (1.1–2.8), p ≤ 0.001). In the mini-SAVR group, cardiopulmonary bypass time was 80 ± 34 min, cross-clamp time was 63 ± 24 min.

Overall 30-day mortality was 1.8% (1.5% and 2.8% in mini-SAVR and TAVI respectively, p = 0.048. Table 2). Surgical patients required more often blood transfusion and experienced more frequently kidney postoperative dysfunction while TAVI patients had a higher need of permanent pace maker insertion, postoperative length of stay was longer in surgical patients (Table 2).

4. Propensity matched cohort

Matching patients with propensity score identified two groups of 386 patients each (Table 1), with mean age of 81 years, similar rate of

renal dysfunction, pulmonary disease, coronary artery disease and similar EuroSCORE II: 3.0% (2.0–4.8) vs 2.9% (2.2–4.4); p = 0.680. In the mini-SAVR group cross-clamp time and cardiopulmonary bypass time were 76 ± 30 min and 59 ± 23 min respectively. There was no difference in 30-day mortality (3.4% in mini-SAVR and 2.3% in TAVI; p = 0.40) and stroke (Table 2) between groups. As in the general population, surgical patients required more often blood transfusion, experienced more frequently kidney postoperative dysfunction and required longer ICU and hospital length of stay while TAVI patients had a higher need of permanent pace maker insertion (Table 2).

5. Discussion

Our data on a recent multicenter large cohort of patients undergone aortic valve treatment either with minimally invasive surgical replacement or transcatheter implantation shows that satisfactory short-term results can be obtained with both techniques. Overall 30-day mortality was 1.8%, a result accomplished in a population with mean age of 74 years and EursoSCORE II of 1.9%.

We decided to focus on the evaluation of the short-term outcomes obtained treating aortic valve pathology either with mini-SAVR or TAVI because the results of the large trials or registries were mainly obtained using full sternotomy in the surgical arm, even in patients considered at intermediate risk [11,12]. We present one of the largest series so far in which a minimally invasive surgical approach represents the comparison to the transcatheter approach.

Despite still ongoing skepticism regarding minimally invasive cardiac surgery, many studies have shown that results obtained reducing surgical exposure and trauma are at least equal than those obtained in full sternotomy [13]. Some robust studies have reported a reduction in ICU length of stay, mechanical ventilation time and postoperative blood loss [14]. Moreover, a significant reduction of the inflammatory reaction and coagulopathy associated with cardiac operations has been observed in minimally invasive aortic valve surgery, giving a possible rationale for the improvement in clinical outcome [15]. In our study, mini-SAVR patients experienced a low 30-day mortality rate (1.5%), a low incidence of stroke (0.6%) and an acceptable blood transfusion requirement (36.1% of the patients), indicating that a minimally invasive approach (either with partial hemi-sternotomy or with right anterior thoracotomy) is safe, feasible and reproducible in the hands
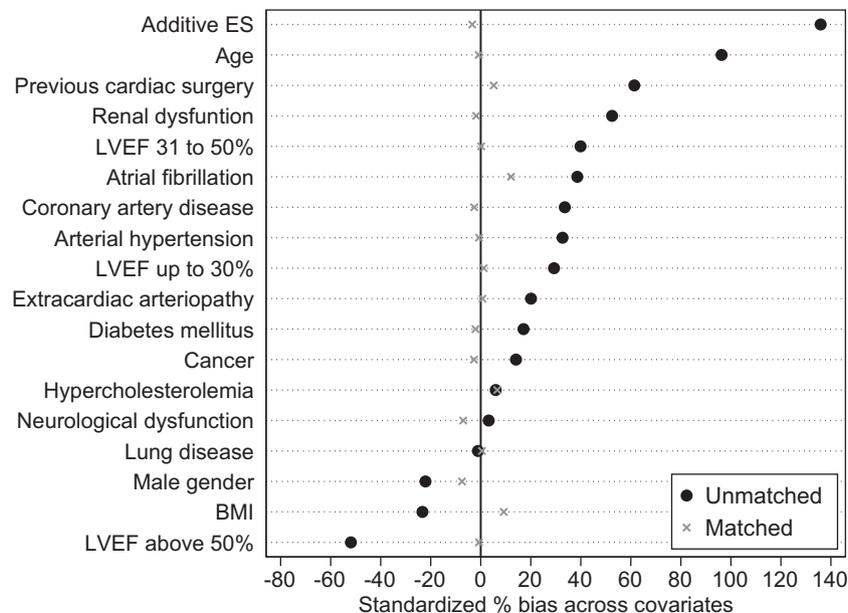

Fig. 1. Absolute standardized differences before and after matching.

Table 1
Characteristics of patients by procedure in the overall population and in the subgroups paired by propensity score.

	Overall				Match by propensity		
	n = 2904	Mini-SAVR	TAVI	p	Mini-SAVR	TAVI	p
		n = 2407	n = 497		n = 386	n = 386	
Male gender	1497 (51.5%)	1286 (53.4%)	211 (42.5%)	<0.001	166 (43.0%)	158 (40.9%)	0.57
Age (years)	74 ± 11	72 ± 11	81 ± 6	<0.001	81 ± 5	81 ± 7	0.94
Body mass index (Kg/m^2)	27.2 ± 4.5	27.3 ± 4.6	26.3 ± 4.1	<0.001	26.6 ± 4.1	26.5 ± 4.2	0.74
Arterial hypertension	2137 (75.0%)	1713 (72.7%)	424 (85.8%)	<0.001	335 (87.5%)	330 (85.9%)	0.58
Diabetes mellitus	619 (21.7%)	482 (20.5%)	137 (27.8%)	<0.001	113 (29.5%)	103 (26.8%)	0.35
Hypercholesterolemia	1568 (55.0%)	1284 (54.5%)	284 (57.5%)	0.23	216 (56.4%)	216 (56.3%)	1.000
Renal dysfunction	177 (6.4%)	83 (3.6%)	94 (20.1%)	<0.001	53 (14.4%)	52 (14.0%)	0.82
Lung disease	679 (24.3%)	567 (24.3%)	112 (23.9%)	0.83	89 (24.1%)	88 (23.7%)	0.93
Previous disabling stroke	53 (1.9%)	42 (1.8%)	11 (2.2%)	0.51	4 (1.0%)	7 (1.8%)	0.37
History of cancer	238 (8.7%)	181 (7.9%)	57 (12.2%)	0.003	42 (11.4%)	41 (11.1%)	0.90
Atrial fibrillation	330 (12.0%)	219 (9.6%)	111 (23.7%)	<0.001	72 (19.6%)	75 (20.2%)	0.85
Peripheral vascular disease	275 (9.7%)	201 (8.5%)	74 (15.0%)	<0.001	53 (13.8%)	50 (13.0%)	0.74
Coronary artery disease	494 (17.4%)	354 (15.0%)	140 (28.7%)	<0.001	95 (24.8%)	95 (24.7%)	1.000
Previous cardiac surgery	156 (5.5%)	52 (2.2%)	104 (21.0%)	<0.001	38 (9.9%)	42 (10.9%)	
Ejection fraction				<0.001			0.56
>50%	2119 (75.0%)	1850 (79.1%)	269 (55.5%)		225 (59.8%)	235 (62.3%)	
31–50%	636 (22.5%)	456 (19.5%)	180 (37.1%)		136 (36.2%)	123 (32.6%)	
≤30%	70 (2.5%)	34 (1.5%)	36 (7.4%)		15 (4.0%)	19 (5.0%)	
EuroSCORE II (%)	1.9 (1.2–3.3)	1.7 (1.1–2.8)	3.3 (2.3–6.0)	<0.001	3.0 (2.0–4.8)	2.9 (2.2–4.4)	0.68

Mean ± Standard Deviation, median (interquartile range) or number (percentage). Renal dysfunction: dialysis or creatinine > 2 mg/dl. The p value of matched data by propensity refers to a univariate conditional logistic regression model.

of different surgeons working in different hospitals. The results achieved by teams of 10 different centers demonstrate the reproducibility of minimally invasive procedures with a short learning curve.

Also the clinical outcome of TAVI patients in our general population is satisfactory, in line with those of published registries [16,17]. We observed a relatively high percentage of permanent pace-maker insertion (19.5%), reflecting the utilization of old and new generation self-expanding valves and mechanically expanded valve, for which PPM insertion has been reported ranging from 37% with the old generation self-expanding devices [18] to 15% with the new ones [19] and 32% with mechanically expanded valves [20].

Propensity score identified surgical patients with clinical characteristics similar to the TAVI cohort; it was able to create 2 groups of patients without apparent differences. Nonetheless propensity matching eliminated the lower risk mini-SAVR patients and the higher risk TAVI ones identifying an overlapping elderly population with several important comorbidities and a relatively high expected 30-day mortality. According to the clinical outcome observed, it appears that in this kind of patients both minimally invasive surgical approach and transcatheter

implantation represent a valid option to treat aortic valve pathology. Thirty-day mortality, incidence of stroke and other minor neurologic complications were not different between groups. Thirty-day mortality, occurred in 2.9% of the mini-SAVR patients and in 2.1% of the TAVI patients, which is slightly lower than the mortality observed in the PARTNER II trial and in line with the results of the SURTTAVI trial, the major trials involving intermediate-risk patients [11,12]. The occurrence of postoperative complications reflects well-known procedure-dependent consequences: mini-SAVR patients had more blood transfusions, more renal function worsening (reported as an increase in kidney injury class [21]) and required more frequently tracheostomy, they had more frequently postoperative atrial fibrillation and required longer ICU and hospital length of stay. TAVI patients required more often permanent pace maker insertion. Some complications however (stroke, blood transfusion) were less frequent in our surgical cohorts compared to the surgical arms of the large trials (Partner II – SURTTAVI).

A recent propensity matched comparison performed on intermediate risk patients [22] highlighted increased 30-day mortality in the surgical patients (4.0% vs 1.1% in surgical and transcatheter arms

Table 2
Post-operative data by procedure in the overall population and in the subgroups paired by propensity score.

	Overall				Match by propensity		
	n = 2904	Mini-SAVR	TAVI	p	Mini-SAVR	TAVI	p
		n = 2407	n = 497		n = 386	n = 386	
Blood transfusion	895 (32.3%)	836 (36.1%)	59 (12.9%)	<0.001	189 (51.1%)	43 (12.0%)	<0.001
Renal function worsening	204 (7.4%)	183 (7.9%)	21 (4.6%)	0.013	56 (15.1%)	15 (4.2%)	<0.001
Atrial fibrillation	672 (26.8%)	660 (30.9%)	12 (3.2%)	<0.001	123 (39.5%)	9 (2.9%)	<0.001
Permanent pacemaker insertion	143 (4.9%)	46 (1.9%)	97 (19.5%)	<0.001	10 (2.6%)	75 (19.4%)	<0.001
Wound infection	13 (0.4%)	12 (0.5%)	1 (0.2%)	0.71	2 (0.5%)	0 (0.0%)	1.000
Reopening for bleeding/complications	77 (2.8%)	70 (3.0%)	7 (1.6%)	0.082	12 (3.2%)	3 (0.8%)	0.032
Re-intubation	53 (2.0%)	48 (2.1%)	5 (1.2%)	0.18	9 (2.5%)	5 (1.5%)	0.37
Tracheostomy	34 (1.2%)	32 (1.3%)	2 (0.4%)	0.080	9 (2.3%)	2 (0.5%)	0.054
Confusion/delirium	37 (1.3%)	36 (1.6%)	1 (0.2%)	0.024	5 (1.4%)	1 (0.3%)	0.34
Non-disabling stroke	7 (0.3%)	7 (0.3%)	0 (0.0%)	0.61	2 (0.5%)	0 (0.0%)	1.000
Disabling stroke	8 (0.3%)	7 (0.3%)	1 (0.2%)	1.000	1 (0.3%)	1 (0.3%)	1.000
Low cardiac output	24 (0.9%)	23 (1.0%)	1 (0.2%)	0.16	4 (1.1%)	1 (0.3%)	0.22
30-days mortality	51 (1.8%)	37 (1.5%)	14 (2.8%)	0.048	13 (3.4%)	9 (2.3%)	0.40
ICU length of stay (days)	2.0 (1.0–1.8)	1.9 (1.5–2.0)	1.0 (0.8–1.5)	<0.001	1.9 (1.7–2.8)	1.0 (0.8–1.7)	<0.001
Post-operative length of stay (days)	7 (6–9)	7 (6–9)	6 (5–9)	<0.001	8 (7–11)	6 (5–9)	<0.001

Mean ± Standard Deviation, median (interquartile range) or number (percentage). Low cardiac output: intra aortic balloon pump and/or inotropic use for >2 days. ICU: intensive care unit. The p value of matched data by propensity refers to a univariate conditional logistic regression model.

respectively), we cannot confirm this finding, based on our observed 30-days surgical mortality; we did not observe a clear advantage of TAVI over surgical treatment when a minimally invasive approach is routinely utilized. In certain patients, with increased age and non-totally invalidating comorbidities, it may be difficult to state that one procedure is superior to the other. Future prospective randomized comparisons between TAVR and SAVR should be performed using minimally invasive approach in the surgical arm with the fundamental question regarding also long-term results.

Some important limitations should be considered for our study. First, the retrospective design contains the bias of the choice of a treatment based on patients' clinical state and physicians' preference. Second, follow-up is at this time unavailable and this is particularly important given that some complications may influence post-procedure survival (i.e.: tracheostomy, paravalvular leak). Third, lack of precise data on paravalvular leak in both groups, particularly for TAVI patients, eliminates an important prognostic factor. Fourth, the choice of the minimally invasive approach (ministernotomy or right mini-thoracotomy) was biased by surgeons' preference and might be associated to different perfusion strategies. Furthermore, our study compares TAVI with the standard surgical prosthesis in procedures performed in a minimally invasive approach, the "new" sutureless prostheses, that have shown to be useful in the "grey zone" between surgery and TAVI, are not evaluated [23].

However, based on the studies in the literature, it can be speculated that the TAVI group has a greater incidence of paravalvular leakage and the initial "price" of surgery can be compensated by improved outcome during follow up [24].

Nonetheless, we present a large multi-center comparison between TAVI and mini-SAVR with propensity score showing that both treatments are safe and effective for elderly patients with comorbidities, highlighting the efficacy of a joint evaluation by the heart-team to direct patients to the proper approach.

Conflict of interest

None declared.

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