NEUTROPHIL TO LYMPHOCYTE RATIO PREDICTS PERMANENT PACEMAKER IMPLANTATION IN TAVR PATIENTS

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Abstract

Introduction. In this prospective multicenter analysis, we aimed to investigate the predictive role of neutrophil/lymphocyte ratio (NLR) in permanent pacemaker implantation (PPI) in patients undergoing transcatheter aortic valve replacement (TAVR). **Material and methods.** 179 consecutive patients without previous PPI underwent TAVR from February 2017 to September 2021. Patients were further divided based on presence (n=48) and absence of conduction abnormalities (CAs) at hospital admission (n=131). **Results** . In patients with previous CAs, NLR values did not differ significantly between patients requiring PPI (n=16, 33%) and those not requiring it. In contrast, in patients with no CAs at hospital admission, NLR values measured at admission and on TAVR day were significantly higher in patients requiring PPI (n=17, 13%) (4.07±3.22 vs 3.01±1.47, p=0.025, and 10.81±7.81 vs 5.84±3.78, p=0.000, respectively). Multivariable analysis showed that NLR at TAVR day was an independent predictor of PPI in patients without CAs (OR 1.294; 95% CI 1.028-1.630; p=0.028), but not in those with previous CAs. ROC curve analysis showed that the cut point was a NLR value of >7.25. Time to PPI was delayed till 21 days in patients without CAs. **Conclusions.** In this prospective study, higher NLR values on the day of TAVR day were associated with an increased PPI rate in patients undergoing TAVR with no previous CAs. It is advisable, being inflammation part of the process, to prolong the time of observation for all patients without CAs till at least 21 days not to miss any new CA necessitating PPI.

INTRODUCTION

Aortic stenosis (AS) is the most common acquired valve disease in elderly patients (1), requiring valve replacement either by surgery or catheter intervention (2) (3).

Transcatheter aortic valve replacement (TAVR) is becoming the preferred approach to treat patients with severe AS (4). Nevertheless, despite growing evidences show good clinical outcomes in AS patients undergoing TAVR, conduction abnormalities (CAs) and the risk of permanent pacemaker implantation (PPI) still rise concerns about TAVR safety. Indeed, it has been recently reported that PPI incidence ranges from 6.6% to 34.8% depending on the use of balloon expandable or self-expandable valves (5) (6) (7).

It is well established that inflammation burden in AS plays a key role in the progression from aortic sclerosis to calcification and that the increased inflammatory activity is closely related to the hemodynamic severity of the disease (8). Neutrophil/lymphocyte ratio (NLR) has been proposed as a marker of inflammation and its ability to predict outcomes has been tested in several cardiac diseases (9). In AS, NLR has been shown

to be related to the severity of calcific AS, left ventricular (LV) disfunction (10), and to be a predictor of major adverse cardiac events (MACE) (11).

Hence, in this retrospective analysis we aimed to investigate the possible role of NLR, as readout of inflammatory state, in PPI in patients with severe AS undergoing TAVR procedure.

MATERIALS AND METHODS

Study population

The study prospectively included 202 consecutive patients with severe, symptomatic AS undergoing TAVR at Gemelli Molise Hospital in Campobasso and at Monaldi Hospital in Naples, from February 2017 to June 2021. Patients requiring PPI before TAVR (n=23) were excluded, resulting in a group of 179 patients.

Data collection

Blood samples were obtained on admission, on the day of TAVR (within two hours after valve implantation) and at discharge. NLR was calculated on admission, on day of TAVR, and at discharge by dividing the number of neutrophils by the number of lymphocytes.

Routine transthoracic echocardiography (TTE) was performed upon hospital admission and discharge, and standard measurements were assessed, including left ventricular ejection fraction (LVEF), and mean transaortic pressure gradient (PG). Computed tomography angiography (CT) was performed before TAVR procedure to assess annular dimensions (area, perimeter, maximum and minimum diameters), eccentricity index (1-minimum diameter/maximum diameter), cover index (100 X (prosthesis diameter-mean annulus diameter)/prosthesis diameter), valve index (100 X (prosthesis diameter/LVOT diameter)). For the assessment of calcification, the FACT score was used (12), while the calcification of single leaflet was qualitatively evaluated with 3 points grading system (1, mild, 2, moderate, 3, severe).

TAVR procedure

All patients were evaluated by the local Heart Team for eligibility.

Patients were treated with self-expandable and balloon-expandable valves via retrograde trans-femoral approach. In particular, Portico (St. Jude Medical, St. Paul, MN), CoreValve Evolute R (Medtronic Inc, Minneapolis, MN), Acurate Neo Valve (Symetis SA, Boston Scientific, Ecublens, Switzerland), and Sapien 3 (Edwards Lifesciences LCC, Irvine, CA) were used in 90, 65, 12 and 35 patients, respectively.

All patients discontinued therapy with beta blockers prior TAVI.

Permanent pacemaker implantation

The primary endpoint of the study was PPI within 30 days after TAVR. The indications for PPI following TAVR were: persistent high degree atrioventricular block (AVB), new onset alternating bundle branch block, pre-existing right bundle branch block (RBBB) with new post-procedure conduction disturbance. Among the 179 included in the study, 48 had previous CAs (11 1st degree AVB, 31 right or left bundle branch block (RBBB or LBBB), 6 AVB and RBBB or LBBB), and 131 had no evidence of CAs at hospital admission. Thus, the analysis included 48 patients with pre-TAVR CAs and 131 patients without pre-TAVR CAs. The two groups were assessed for new onset CAs requiring PPI (Table 1).

The study protocol was approved by our local institutional review board (#000127/2017). The present study complies with the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using IBM SPSS 21 statistical software. Continuous and categorical variables are reported as mean±standard deviation (SD) or as percentages, respectively. Continuous variables were compared between two groups using the t-test and the ANOVA model for repeated measures was performed and validated using Mauchly's test of sphericity with Greenhouse-Geisser correction. A stepwise

logistic regression multivariable analysis was performed, to assess the simultaneous effect of several variables on the primary outcome (PPI). The variables included in the analysis were LVEF, age, sex, CRP, mean aortic PG, FACTS score, implantation depth (mean and non-coronary cusp), valves types, bicuspid aortic valve, non-coronary cusp calcification, NLR at any moment. A ROC curve analysis was applied to find a cut point, if necessary. A p value (two sided) of less than 0.05 was considered significant.

RESULTS

Thirty-three patients out of 179 (18%) underwent PPI within 30 days after TAVR. No differences were found in clinical, echocardiography and CT and procedural variables, but in higher non coronary cusp calcification and in higher prevalence of patients with CAs in PPI group (Table 1 supplement).

Patients undergone PPI showed higher levels of neutrophils (7.9±3.4 vs 6.6±3.0, p 0.032) and NLR at TAVR day (8.2±6.3 vs 6±3.6, p 0.010), with no difference in other biochemical variables (Table 1 supplement). NLR at discharge was significantly higher in patients with previous CAs.

Multivariable logistic regression demonstrated that higher NLR at TAVR day (OR 1.269, 95% CI 1.024-1.571, p 0.029), higher implantation depth (mean) (OR 1.449, 95% CI 1.060-1.081, p 0.020), first degree AVB (OR 40.389, 95% CI 1.824-894.312, p 0.019), first degree AVB plus RBBB/LBBB (OR 35.127, 95% CI 1.328-929.0123, p 0.033) were associated with PPI after TAVR procedure (Table 2 supplement).

Analysis between groups

Of 179 patients, 48 had CAs before TAVR and 131 had not (Table 1). As expected, PPI rate after TAVR were higher in patients with previous CAs (33.3% vs 13%, p 0.002). Median time to implant was similar in both groups: 2 days (1-6.9) in patients with versus 2.5 days (1-7.1) in patients without CAs, p 0.894. In this latter group, 1 patient underwent PPI 21 days after the procedure.

Baseline demographic and clinical characteristics and CT variables were similar in the two groups. The only significant differences were a higher rate of chronic renal failure and a lower rate of advanced NYHA class (III-IV) in patients with previous CAs.

To analyze a possible role of NLR in predicting PPI, patients were stratified by PPI need (Table 2).

In patients with CAs, CRP levels, neutrophil count and NLR at any moment (fig. 1) did not differ between patients receiving and those not receiving PPI.

In patients without CAs, NLR values on the day of TAVR and at upon admission were significantly higher in patients receiving PPI (fig. 2). In addition, non-coronary cusp calcification score and eccentricity index, as assessed by CT, were significantly higher in patients receiving PPI. On the contrary, implantation depth (mean, non-coronary cusp and left coronary cusp implantation depth) did not differ between patients receiving and those not receiving PPI.

Multivariable logistic regression confirmed that NLR at TAVR day was an independent predictor of PPI (OR 1,294; 95% IC 1,028-1,630; p 0,028).

ROC curve analysis showed that a NLR ratio of >7.25 at TAVR day was associated with a higher prevalence of PPI in patients without CAs (AUC 0.716; sensibility 65% and specificity 73%, p 0.003) (fig. 3).

DISCUSSION

The main finding of this study is that NLR, a marker of inflammation, is significantly associated with PPI in patients undergoing TAVR procedure, but only in those without previous CAs. Multivariable analysis showed that only NLR at TAVR day analysis (within two hours after the procedure) was significant, avoiding than any predictive strength to this variable.

TAVR is an established alternative to surgical valve replacement for high and low surgical risk patients with severe AS but is associated to an increased risk of high-grade AVB requiring PPI (4). The incidence of PPI

has been reported as 6.6% to 34.8% depending on the use of balloon expandable or self-expandable valves (5) (6) (7).

Several aspects affecting the occurrence of PPI have been identified, some of which depend on the procedure itself and can be prevented, such as depth of valve implantation (13) and use of self-expandable bioprosthetic valves. Other risk factors for post-TAVR PPI, such as age, systemic arterial hypertension, type 2 diabetes mellitus, history of myocardial infarction, are non-preventable. Pre-existing CAs, including RBBB and LBBB, have been reported as the most powerful predictors for PPI. Our study confirmed this finding.

There is an established relationship between inflammation and calcific aortic valve disease (14). Nevertheless, the identification of a biochemical marker of disease progression has not been achieved, so far. CRP is considered a reliable marker of systemic inflammation and while it has been significantly associated with progression of atherosclerosis (15), its role in the progression of calcific AS is still debated. Indeed, data from the Cardiovascular Health Study (16) showed a poor predictive value of CRP on progression of subclinical calcific aortic valve disease. On the other hand, in 135 patients with asymptomatic AS, CRP levels were found to be significantly associated with disease severity, progression, and prognosis (17). More recently, in TAVR candidates with severe AS, high sensitivity CRP at baseline predicted post-TAVR mortality and its variation at 3 months follow-up was associated to increased mortality, thus confirming its predictive power (18).

In our population CRP levels were not associated with severity of aortic disease (data not shown). Furthermore, in between groups analysis no significant differences in CRP between subjects receiving and not receiving PPI.

NLR has been proposed as inflammatory marker in several cardiovascular diseases (9). In AS it showed significant correlation with calcific AS severity, LV disfunction (10), and MACE (11). In our population, neutrophil and lymphocyte count and their ratio (NLR) were assessed at different timepoints across the TAVR procedure. NLR at TAVR day was significantly higher in patients underwent PPI and, at multivariate analysis, was predictive of PPI together with implantation depth, first degree AVB and first degree AVB plus RBBB/LBBB. However, this finding was driven only by patients without previous CAs, where we observed significantly higher NLR values at implantation day in patients receiving PPI.

While the role of inflammation in the progression of AS is well established (8), we found that the behavior of components of the innate immune response may represent a readout of TAVR-related CAs. The analysis at different timepoints across the TAVR procedure of neutrophils and lymphocytes count and their ratio provided a hint on the innate immune state both in the setting of chronic inflammation before the intervention and following an acute injury represented by the TAVR procedure. It has been reported that early after acute ischemic injury, neutrophils are the first recruited inflammatory cell population (19). Our report highlights a possible relationship between the acute-over-chronic inflammatory response to the TAVR-induced injury and the need of PPI. During TAVR procedure, anatomic factors such as membranous septum length (13) and the severity or distribution of left coronary cusp leaflet calcification can play an important role in prediction of PPI which can be enhanced by an increased inflammatory status, the extent of which might affect the need of PPI.

NLR at TAVR day is related to higher PPI, but after the procedure. ROC curve analysis provided a cut point where the possibility of PPI is more likely to happen. As we observe the variable, but cannot prevent it, the association of no pre-procedural CAs and post-procedural NLR>7.25 advices to prolong the observation of such patients, who can need PPI even after many days from the procedure, for at least 21 days.

LIMITATION OF THE STUDY

This is prospective, but observational study and, even if most variables are similar in both groups, it is not possible to reproduce the validity of a randomized study. Moreover, most of bioprostheses used are self-expandable, a well known risk factor for PPI, but their presence constant in both groups. We think that the findings of this study can be valid in general, as inflammation is a risk factor for the progression of many

valvular diseases.

CONCLUSION

Results of our study suggest that inflammation can play an important role during TAVR and that NLR at TAVR day could be an easy-to-calculate factor that can provide new insights in the mechanisms of new CAs after TAVR. Even if NLR is not predictive, as the value becomes significant only after the procedure, in patients without pre-procedural CAs and NLR at TAVR day >7.25, attention has to be paied to the possibility of late development of a new CAs that needs PPI for at least 21 days. Further studies are warranted to confirm the findings of our research.

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TABLES

Table 1. Baseline characteristics of patient with or without conduction disturbances

Clinical characteristics	No Previous Conduction defect (n=131)	Previous Conduction defect (n=48)	P value
Age	80.07±7.19	80.43±6.12	0.758
Sex Male n (%)	46 (35)	20 (42)	0.424
CAD n (%)	46 (35)	11 (23)	0.115
NYHA III-IV n (%)	85 (65)	22 (46)	0.023
Previous stroke n (%)	2 (1,5)	1 (2)	0.803
Diabetes n (%)	39 (30)	21 (44)	0.086
Hypertension n (%)	111 (85)	45 (94)	0.108
PAD n (%)	22 (17)	10 (21)	0.549
COPD n (%)	29 (22)	14 (29)	0.332
CKD n (%)	30 (23)	21 (43)	0.010
PPI n (%)	17 (13)	16 (33)	0.002
Echo variables			
EF (%)	53.28±8.57	53.91±4.69	0.632
Mean PG mmHg	48.84±14.04	47.23±13.13	0.502
CT variables			
Eccentr index	17.38±6.37	15.98±5.95	0.357
Valve index	112.16±8.17	111.44±8.53	0.734
Cover index	14.12±14.72	11.59±6.81	0.445
FACT score	6.89±3.44	5.85±3.21	0.213
LVOT calcif n (%)	33 (25)	18 (38)	0.222
Asym cuspid calcif n (%)	90 (69)	39 (81)	0.319
RCC calcification (1-3)	1.33	1.33	0.988
LCC calcification (1-3)	1.30	0.95	0.152
NCC calcification (1-3)	1.67	1.90	0.382
Procedural variables			
Self Expandable n (%)	115 (88)	33 (69)	0.003
Balloon Expandable n (%)	16 (12)	15 (31)	0.003
Size (#)	26.9±2.9	26.4±2.8	0.343
Balloon post dilat SE n (%)	37 (28)	8 (18)	0.189

Clinical characteristics	No Previous Conduction defect (n=131)	Previous Conduction defect (n=48)	P value
Balloon post dilat BE n (%)	0 (0)	5 (10)	0.223
Biochemical variables			
Hgb g/dl	12.2±1.69	12.2±1.64	0.853
CRP mg/l	4.87±6.88	4.35±5.71	0.700
Neutrophils admission	4.76±1.63	4.88±1.69	0.667
Lymphochytes admission	1.84±1.91	1.72±0.58	0.658
Neutrophils impl day	6.79±3.06	7.16±3.42	0.486
Lymphochytes impl day	1.46±1.90	1.28±0.50	0.510
Neutrophils discharge	4.85±1.79	5.45±2.23	0.068
Lymphocytes discharge	1.67±1.39	1.47±0.46	0.328
NLR admission	3.15±1.81	3.04±1.26	0.693
NLR impl day	6.49±4.77	6.24±3.74	0.750
NLR discharge	3.32±1.74	4.07±2.20	0.021

Legend: CAD, coronary artery disease; PAD, peripheral artery disease; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; PPI, permanent pacemaker implantation; EF, ejection fraction; PG, pressure gradient; AVB, atrioventricular block; IV cond, intraventricular conduction; RBBB, right bundle branch block; LBBB, left bundle branch block; FACT, Free State aortic valve calcium computed tomography; LVOT, left ventricular outflow tract; Asym cuspid calcif, asymmetric cuspid calcification; RCC, right coronary cusp; LCC, left coronary cusp; NCC, non-coronary cusp; SE, self expandable; BE, balloon expandable; Hgb, hemoblogin; CRP, C reactive protein; NLR, neutrophils to lymphocytes ratio.

Table 2. Baseline characteristics of patient with or without conduction disturbances, stratified on the need of permanent pacemaker implantation.

	No Previous Conduction Defect	No Previous Conduction Defect	No Previous Condu
	no PPI (n=114)	PPI (n=17)	P value
Clinical characteristics			
Age	79.54±7.45	83.58±3.65	0.030
Sex Male n (%)	42 (37)	4 (23)	0.287
CAD n (%)	41 (36)	5 (29)	0.584
NYHA III-IV n (%)	68 (60)	16 (94)	0.006
Previous stroke n (%)	1 (0.9)	1 (5,9)	0.120
Diabetes n (%)	35 (31)	4 (23)	0.536
Hypertension n (%)	95 (83)	16 (94)	0.247
PAD n (%)	19 (17)	3 (17)	0.933
COPD n (%)	26 (23)	3 (18)	0.636
CKD n (%)	24 (21)	5 (29)	0.584
Echo variables			
EF (%)	53.09±8.91	54.47±5.94	0.541
Mean PG mmHg	48.21±13.40	53.12±17.77	0.193
CT variables			
Eccentr index	16.73±6.53	21.27±3.40	0.021
Valve index	112.10±8.46	112.53±6.21	0.880
Cover index	14.47±15.64	11.82±5.32	0.581
FACT score	6.82±3.44	7.33±3.49	0.636
LVOT calcif n (%)	29 (26)	3 (17)	0.492
Asym cuspid calcif n (%)	80 (70)	11 (67)	0.835
RCC calcification (1-3)	1.27	1.67	0.217

	No Previous Conduction Defect	No Previous Conduction Defect	No Previous Condu
LCC calcification (1-3)	1.27	1.50	0.491
NCC calcification (1-3)	1.53	2.50	0.004
Procedural variables			
Self Expandable n (%)	98 (86)	17 (100)	0.101
Balloon Expandable n (%)	16 (14)	0 (0)	0.101
Size (#)	26.8±2.8	27.1±3.6	0.687
Balloon post dilat SE n (%)	33 (29)	3 (19)	0.393
Balloon post dilat BE n (%)	0 (0)	0 (0)	-
Mean Impl Depth (mm)	7.43±3.54	8.38±3.21	0.323
Impl Depth NCC (mm)	6.97±3.94	8.17±3.61	0.262
Impl Depth LCC (mm)	7.90±3.53	8.59±3.62	0.476
Hematological variables			
Hgb g/dl	12.2±1.7	12.1±1.5	0.919
CRP mg/l	4.7±6.6	5.6±8.5	0.663
Neutrophils admission	4.70±1.60	5.19±1.77	0.243
Lymphocytes admission	1.88±2.04	1.60±0.63	0.569
Neutrophils impl day	6.44±2.74	9.10±4.05	0.001
Lymphochytes impl day	1.53±2.02	1.04±0.40	0.329
Neutrophils discharge	4.75±1.79	5.51±1.68	0.101
Lymphocytes discharge	1.68±1.57	1.60±0.68	0.821
NLR admission	3.01±1.47	4.07±3.22	0.025
NLR impl day	5.84±3.78	10.81±7.81	0.000
NLR discharge	3.21±1.56	4.04±2.59	0.068

Legend: CAD, coronary artery disease; PAD, peripheral artery disease; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; PPI, permanent pacemaker implantation; EF, ejection fraction; PG, pressure gradient; AVB, atrioventricular block; IV cond, intraventricular conduction; RBBB, right bundle branch block; LBBB, left bundle branch block; FACT, Free State aortic valve calcium computed tomography; LVOT, left ventricular outflow tract; Asym cuspid calcif, asymmetric cuspid calcification; RCC, right coronary cusp; LCC, left coronary cusp; NCC, non-coronary cusp; SE, self expandable; BE, balloon expandable; Impl, implantation; Hgb, hemoblogin; CRP, C reactive protein; NLR, neutrophils to lymphocytes ratio.

FIGURE

Figure 1. NLR values across the TAVR procedure in patients with conduction disturbances.

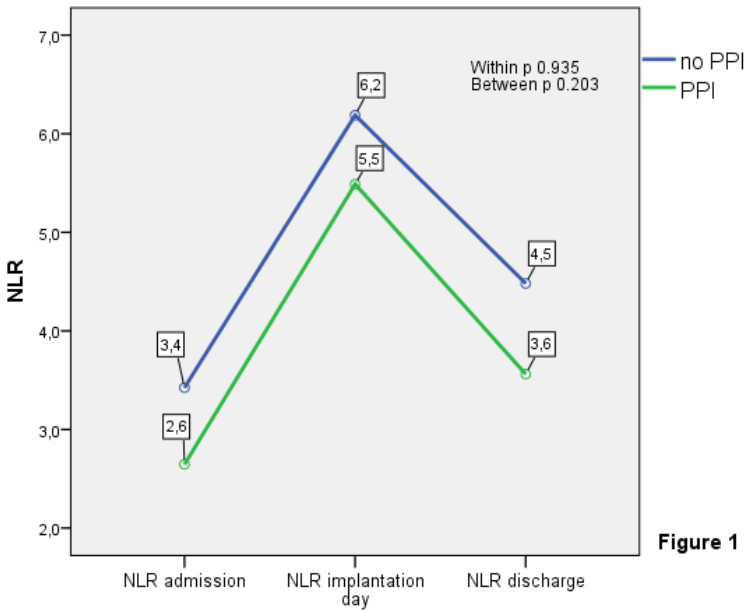

Figure 1

Figure 2. NLR values across the TAVR procedure in patients without conduction disturbances.

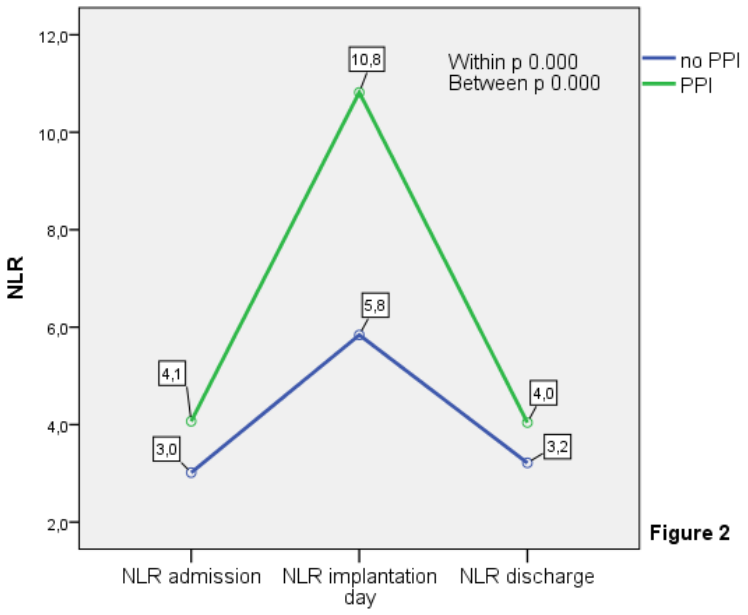

Figure 2