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Annals of Cardiovascular Diseases

Research Article

Livanova Perceval Prosthesis to Treat Elderly Frail Patients: Immediate and Short-Term Results

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Submitted: 20 April 2016

Accepted: 26 July 2016

Published: 30 July 2016

Keywords

- Suture less bioprosthesis
- Aortic valve stenosis
- Elderly
- Medium risk
- Livanova Perceval™

Abstract

Background: High risk older patients needing surgery for aortic valve stenosis may benefit from low-impact procedures. Suture less prostheses allow a more expedite procedure and might induce better clinical results. Aim of this study was to compare early and short-term clinical performance of Livanova Perceval in a frail patient's population.

Methods: From May 2012 to January 2014 twenty one patients (mean age 80.6 ± 4.3 years), received a Sorin Perceval S™ (Group 1). Forty three patients treated with conventional AVR were selected as a control group (mean age 79.1 ± 3.3 years) (Group 2). The mean Logistic Euro score was 15.5% ± 7.3 in Group 1 and 14.7% ± 6.1 in Group 2; 14 patients (66%) of Group 1 and 26 patients (60%) of Group 2 were in NYHA functional class III/IV.

Results: The observed 30 days mortality rate was zero in Group 1 and 9% in Group 2 (*p* ns). The mean cross-clamp and cardiopulmonary bypass time were significantly lower in Group 1 for isolated AVR (31.3 ± 4.6 vs. 45.6 ± 10.3 minutes $p<0.0001$ and 45.2 ± 6.6 vs. 59.1 ± 10.6 $p<0.0001$). In Group 1 there was no evidence of paraprosthesis leak, myocardial infarction or acute kidney injury and the postoperative hospital stay was 7.2 ± 2.4 days. The need of pacemaker implantation was significantly higher in Group 1. At 24 months follow up, the overall survival was 89.1 ± 11% in Group 1 vs. 83.6 ± 16.4% in Group 2 (*p*ns) and freedom from adverse events was 84 ± 16% in Group 1 vs. 65.2 ± 34.8% in Group 2 (*p*ns).

Conclusions: The Livanova Perceval bioprosthesis seems to be an excellent option for elderly patients needing aortic valve replacement at increased risk for surgery. The incidence of early AV block represents the only relevant drawback of this device.

INTRODUCTION

Aortic stenosis (AS) is the most common valve disease in older patients [1]. During 2011, in Europe, about one million people suffered from this condition, therefore considering the increase in life expectancy, we can expect that this disease will affect about 2.1 million people in 2050 [2].

Giving that, patients suffering severe aortic valve stenosis needing surgery, will dramatically increase. Moreover most of them will be elderly with associated comorbidities.

Aortic valve replacement (AVR) has been clearly showing to be a valid optionable to restore a normal life expectancy [3] and it is a safe and effective procedure in aged patients at low risk for surgery. Although transcatheter aortic valve implantation (TAVI) represents the main solution for patients with prohibitive surgical risk [4], which option should be offered to patients at intermediate-high operative risk is still under investigation.

Suture less prosthesis such as the Livanova Perceval; have been developed to treat this kind of patients. Their quick implantation allows obtaining shorter cardiopulmonary bypass (CPB) and cross-clamp times, features considered a significant advantage in frail patients.

Aim of this study was to compare the immediate and short-term follow-up results of conventional aortic valve replacement (C-AVR) and aortic valve replacement using a suture less prosthesis (S-AVR) in a medium-risk population.

MATERIALS AND METHODS

We selected 105 consecutive patients older than 75 years (mean age 80.3 ± 4.6 y/o, Logistic Euroscore between 10 and 20%) affected by severe aortic stenosis and surgically treated at Tor Vergata University of Rome between June 2012 and December 2013.

With the purpose to obtain a uniform cohort 25 patients were excluded from the study population due to anatomical and functional characteristics according to the inclusion criteria proposed by Livanova to implant a Perceval suture less valve (7 bicuspid aortic valve, 7 pure aortic regurgitation, 11 aortic root dilation).

Moreover, urgency and emergency cases (7), patients who underwent mini-sternothomy (2), patients with incomplete imaging of the aortic root (2) and patients implanted with suture less prosthesis different by Livanova Perceval (5), were also excluded.

The remaining population included 64 patients: Group 1 including 21 patients treated with S-AVR using Livanova Perceval (16 female (76%), mean age 80.6 ± 4.3) and Group 2 including 43 patients treated with C-AVR (28 female (65%), mean age 79.1 ± 3.3).

The two groups were similar for age, sex and main cardiovascular risk factors distribution. The main clinical characteristics are summarized in (Table 1). All patients underwent preoperative echocardiographic evaluation. Echo parameters were similar in the two groups although patients in Group 1 had a more sever aortic valve stenosis. Table (2) resumes echo data.

Surgical technique and intraoperative features

A complete median longitudinal sternotomy was performed in all cases. Normothermic cardiopulmonary bypass was instituted with arterial cannulation into the distal ascending aorta and venous drainage was obtained via right atrium. Intermittent anterograde warm blood cardioplegia was administered every 20 minutes.

In Group 1 a transverse aorthotomy was performed 3 cm above the sinotubularjuction. In all cases complete decalcification of the aortic annulus was performed with the usual technique in order to create a circular shaped annulus and removing eccentric/bulky protruding intra-luminal calcifications. In Perceval cases extensions of decalcification did not interested the intra-annular position and were less extreme than in conventional prosthesis. The correct size of the prosthesis was obtained according the criteria proposed by Livanova. Each prosthesis has sizers with transparent obturator and a white obturator. When the transparent obturator passes through the annulus and the white obturator does not, the valve size identified on the sizer handle must be chosen. In all cases preoperative echoes showed the ratio between the sinotubular junction and the annulus diameter is ≤ 1.3.

After choosing the appropriate size, the Perceval prosthesis was implanted using three 4-0 polypropylene sutures guides placed at nadir of each commissure; a balloon was inflated for 30 seconds at 4 atmospheres. The guide sutures were removed at the end of the procedure.

Conventional AVR was performed in the usual way securing the prosthesis to the annulus using 10 to 13 U-shaped stitches of 2-0 synthetic braided pledgeted sutures. In the conventional AVR Group 60% of patient reciveda Sorin Mitro flow prosthesis while the remaining a Perimount Magna Ease. In case of associated CABG distal vein anastomosis were executed always before AVR. The LAD was revascularizated using left ITA.

Data collection and statistical analysis

Several variables including age, sex, hypertension, smoking habits, NYHA class, renal and pulmonary function, diabetes, polivascular disease, presence of associated coronary disease, left ventricle ejection fraction, aortic valve gradients, aortic valve area, grade of aortic valve regurgitation were analyzed to describe the population. Surgical risk was evaluated for all patients using the Logistic Euro score Calculator. Intra and postoperative data including cardiopulmonary bypass time, cross-clamp time, need for transfusions, ventilation time, ICU stay, total postoperative length of stay and incidence of major postoperative complication including in-hospital mortality were evaluated. In-hospital mortality was defined both as event occurred within 30-days after operation and event occurred in patient never discharged. Major not cardiac complications was defined according to the international guidelines: stroke was defined as permanent neurological deficit confirmed at CT scan; renal complication as necessity of continuous venous hemofiltration; pulmonary insufficiency as a ventilation time > 48 h, need of reintubation or need of positive end-respiratory pressure by mask following estuation.

Follow-up was completed by a single investigator during one month period (June 2015). Follow up was 95% complete with a mean duration of 18.8 ± 11 months (median 19 months). During the follow up period, 55 survivors patients received clinical examination, 12 leads EKG and transthoracic echocardiography exams. These data were compared with data recorded during in hospital stay. Published guidelines of Society of Thoracic Surgeons and American Association of Thoracic Surgery were used to report valve-related morbidity (endocarditis, major bleeding and thromboembolism) and death.

Student's t test for continuous data and the $\chi 2$ or Fisher's exact test for categorical data was used.

Freedom from cardiovascular events during follow-up was expressed as mean values plus or minus 1 standard deviation, and computed by using the Kaplan-Meier method; the Mantel Cox log-rank test was used to compare event-free survival among subgroups. All other continuous values were expressed as mean plus or minus 1 standard deviation of the mean. All P values less than 0.05 were considered statistically significant.

RESULTS

In hospital results

Four patients (19%) of Group 1 and 19 patients (45%) of Group 2 underwent simultaneous coronary artery bypass

grafting (CABG) (*p=ns*). Regarding the CPB time and cross-clamp time some differences was observed. In the all cohort mean CPB time was 53.4 ± 19 minutes in Group 1 vs. 80 ± 29.4 minutes in Group 2 (p=0.004). Mean cross-clamp time was 36.7 ± 13.3 vs. 59.7 ± 20.9 minutes (p<0.001). CPB time and cross-clamp time in isolated AVR surgery were 45.2 ± 6.6 vs. 59.1 ± 10.6 minutes (p<0.0001) and 31.3 ± 4.6 vs. 45.6 ± 10.3 minutes (p<0.0001) in Group 1 and Group 2 respectively. Furthermore, if we analyze only patients, who underwent AVR and CABG, mean CPB time was 88.2 ± 14 minutes in Group 1 vs. 105 ± 24.9 minutes in Group 2 and mean aortic cross clamp time was 59.5 ± 14.6 vs. 76.8 ± 17.3 minutes in Group 1 and 2respectively. These differences were not statistically significant. With respect to the size of valve prostheses implanted in both groups a statistically significant difference was observed, since patients in Group 1 received prosthesis larger than those implanted in Group 2 (22.5 ± 1.5 mm in Group 1 vs 20.8 ± 1.3 mm in Group 2, p=0.0005) (Table 3).

Patients of Group 1 had a slightly shorter ICU stay (2.2 ± 1.5 vs. 4.4 ± 7.4 days; *p*ns) and total postoperative length of stay (7.3 ± 2.5 vs. 8.4 ± 9.2; *p*ns). A major need for transfusion was observed in Group 2 (1.5 ± 1.9 vs. 3 ± 3.6 PRBC for patient p=0.03) (Table 4).

Postoperative atrial fibrillation (3 vs. 18 cases, p=0.04) and acute kidney injury needing continuous haemofiltration (0 vs. 8 pt.; p<0.05) was less common in S-AVR group. On the other hand, patients of Group 1 experienced more frequently a complete atrio-ventricular (AV) block needing pacemaker implantation (5 vs. 1 cases respectively in Group 1 and in Group 2; p=0.01). Other postoperative complication including in-hospital mortality is summarized in (Table 4).

Follow up results

During the follow-up period three late deaths occurred, two in Group 1 and one in Group 2. Cause of death were a fatal arrhythmias and massive stroke secondary to embolism in Group 1 and sepsis secondary to deep sternal wound infection in Group 2. Overall 36 months survival was 90.5% in Group 1 vs. 83.9% in Group 2 (*p*ns) (Figure 1).

Clinical status was recorded during examination and 2 patients (9.5%) of Group 1 vs. 4 patients (9.3%) were in NYHA class III. No patient was in NYHA class IV. Freedom from re-admission for cardiovascular disease at 36 month was respectively 94.7% and 79.4% in Group 1 and Group 2 (*p*ns) (Figure 2).

A pacemaker test was performed in all patients that needed implantation. With respect to the suture less Group, three of the five patients were in sinus rhythm with no more need for stimulation. Concerning main valve-related events, we reported one fatal embolic event in Group 1 vs. 0 in Group 2; none endocarditis in Group 1 vs. one in Group 2; no redo operation, paravalvular leakage and haemorrhagic events in all cases. Overall, freedom from adverse events (intended as association of mortality, need for re-hospitalization, and valve related events) at 36 months was 85.7% in Group 1 vs. 75.2% in Group 2 (*p*ns) (Figure 3).

DISCUSSION AND CONCLUSION

The most recent epidemiological studies definitively show that the cardiac surgeon will face more and more frequently

Table 1: Main Preoperative Features.

Characteristic	Group1 (n=21)	Group2 (n=43)	*p* Value
Age, years	80.6 ± 4.3	79.1 ± 3.3	ns
Female gender, n (%)	16 (76)	28 (65)	ns
NYHA III/IV, n (%) BSA (m^2)	14 (66) 1.75 ± 0.17	26 (60) 1.75 ± 0.13	ns ns
Hypertension, n (%)	19(90)	41(95)	ns
Obesity, n (%)	6(29)	16(37)	ns
Diabetes mellitus, n (%)	3(15)	11(26)	ns
Chronic renal dysfunction, n (%)	7(33)	11(26)	ns
Chronic obstructive pulmonary disease, n (%)	3(15)	0	0.03
Peripheral vascular disease, n (%) LVEF (%)	4(20) 57 ± 14	12(28) 55 ± 12	ns ns
Logistic EuroScore	15.5% ± 7.3	14.7% ± 6.1	ns
Coronary Artery Disease, n (%)	6(29)	19(45)	Ns

NYHA: New York Heart Association Class; BSA: Body Surface Area; LVEF: Left Ventricular Ejection Fraction

Table 2: Preoperative Echocardiographic Variables.

Variable	Group1 (n=21)	Group2 (n=43)	*p* Value
Left Ventricle			
Left ventricular end-diastolic diameter, mm	49.7 ± 8.1	50.1 ± 6.2	ns
Left ventricular end-systolic diameter, mm	32.2 ± 10.3	32.5 ± 6.5	ns
Left ventricular septum thickness, mm	15.4 ± 3.4	15 ± 3	ns
Left ventricular ejection fraction, (%)	57 ± 14	55 ± 12	ns
SPAP, mmHg	35.9 ± 5.5	40 ± 11.8	ns
Aortic annulus, mm	19.8 ± 1.4	20.4 ± 2	ns
Aortic root, mm	29.8 ± 2.8	30.7 ± 3	ns
GST, mm	26.7 ± 5.9	26.1 ± 4.8	ns
Ascending aorta, mm	32.7 ± 5.9	33.7 ± 4.8	ns
Aortic Valve Max gradient (mmHg) Medium gradient (mmHg) AVA (cm^2) Aortic Insufficiency, mean value/4+	 99.1 ± 43.6 59 ± 26 0.44 ± 0.22 0.85 ± 0.75	 80.4 ± 23.3 51 ± 15.1 0.64 ± 0.23 0.68 ± 0.8	 0.03 ns 0.008 ns

SPAP: Systolic Pulmonary Artery Pressure; AVA: Aortic Valve Area

Table 3: Intra-operative Variables.

Variable	Group1 (n=21)	Group2 (n=43)	*p* Value
CPB, minutes AVR isolated AVR+CABG All	 45.2 ± 6.6 88.2 ± 14 53.4 ± 19	 59.1 ± 10.6 105 ± 24.9 80 ± 29.4	 <0.0001 ns 0.004
Aortic cross-clamp, minutes AVR isolated AVR+CABG All	 31.3 ± 4.6 59.5 ± 14.6 36.7 ± 13.3	 45.6 ± 10.3 76.8 ± 17.3 59.7 ± 20.9	 <0.0001 0.07 <0.0001

Associated CABG procedures, n (%) Distal anastomosis performed, n	4(19) 1.75 ± 0.9	19(45) 1.74 ± 0.7	ns ns
Valve prosthesis size, mm	22.5 ± 1.5	20.8 ± 1.3	0.0005
CPB: Cardio-pulmonary bypass; AVR: Aortic Valve Replacement; CABG: Coronary-artery bypass graft			

Table 4: Postoperative Course.

	Group1 (n=21)	Group2 (n=43)	*p* Value
In-hospital mortality, n (%)	0	4(9)	ns
Atrial Fibrillation, n (%)	3(15)	18(41)	0.04
AKIneedingcontinuoushaemofiltration	0	8(18)	0.05
Major bleedings, n (%)	2(9)	4(9)	ns
Paravalvular leak, n (%)	0	1(2)	ns
Need for pacemaker implantation, n (%)	5(24)	1(2)	0.01
Stroke, n (%)	0	4(9)	ns
Respiratory failure, n (%) ICU stay, days Postoperative stay, days PRBC, unit	1(5) 2.2 ± 1.5 7.3 ± 2.5 1.5 ± 1.9	8(18) 4.4 ± 7.4 8.4 ± 9.2 3 ± 3.6	ns ns ns 0.03
AKI: Acute Kidney Injury; ICU: Intensive Care Unit; PRBC: Packed Red Blood Cells			

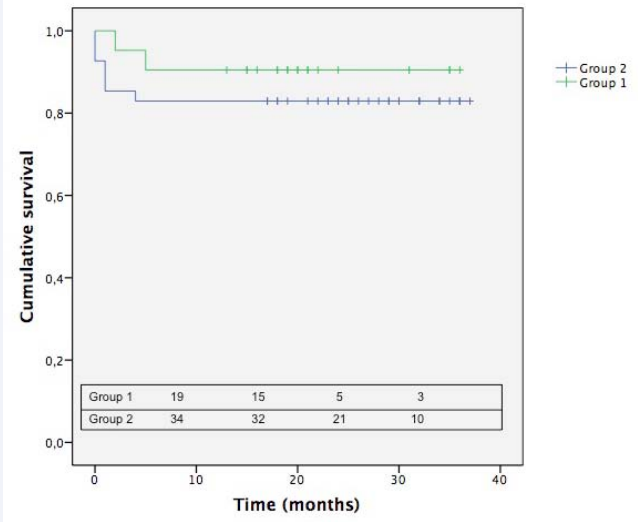

Figure 1 Overall 24 month survival, (*p* NS).

patients affected by severe aortic stenosis with high risk surgical profile [2,6].

Actually conventional aortic valve replacement represents the best option for elderly patients at low-risk [3] where as transcatheter aortic valve prosthesis implantation is a good solution for patients defined at prohibitive risk by an heart team [4]. Concerning the patients at intermediate risk, currently defined *agrey zone* [7], there is a lack of knowledge determining an overlapping of treatment between patients who need surgery that go to TAVI and vice-versa. The best therapeutic choice for this large group of patients remains undefined.

In order to minimize the impact of surgery, the reduction of aortic cross-clamp and cardiopulmonary bypass times seems to be crucial. The achievement of this goalis associated with better clinical outcome, especially in patients with associated comorbidities [8].

The introduction in the surgeon armamentarium of suture less aortic valve prosthesis has contributed to reduce the operating times, both during isolated or combined AVR [9].

Since May 2012, the Sorin Perceval S™ is available at Tor Vergata University of Rome. The aim of the present study is to analysethe impact in choosing a suture less prosthesis on clinical outcomes of intermediate-high risk patients surgically treated.

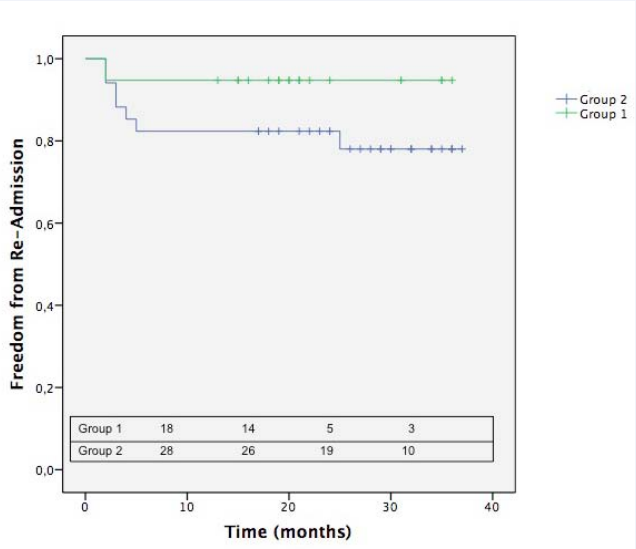

Figure 2 Freedom from re-admissionat36months, (*p* NS).

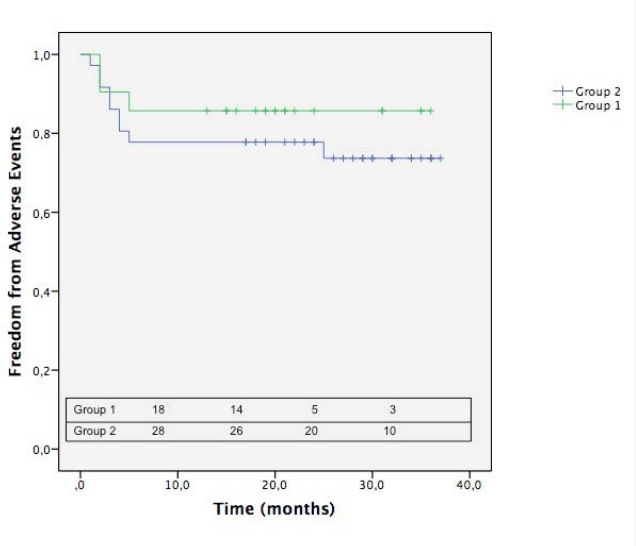

Figure 3 Freedom from adverseeventsat36months, (*p* NS).

For this purpose, we selected a specific population undergoing to implantation of the prosthesis: the average age was 80 years, and the mean Logistic Euro score was 15%, while AVR performed in a conventional manner, in patients without associated comorbidities, provides 2-3% of surgical risk [10].

In order to evaluate the efficacy and safety of this prosthesis, the immediate and follow-up results were compared with those of a cohort of patients selected to be homogeneous in age and comorbidities. Suture less prosthesis implantation showed shorter aortic cross clamp and extracorporeal circulation times both in patients undergoing isolated aortic valve replacement and in cases with associated myocardial revascularization. These results confirmed data already available in the literature [11].

Although in the study population treated by Livanova Perceval™ prosthesis the mean Logistic Euroscore was 15%, no deaths were observed. On the other hand 9% of exitus was recorded in C-AVR group. The difference in observed mortality between the two groups only reaches the limits of statistical significance probably due to the reduced power of the statistical tests related to the low sample size. A larger number of patients will be necessary to more accurately assess the trend of this variable.

Despite the high risk profile in S-AVR group the incidence of the most common complications such as a paravalvular leak (n. 0), perioperative myocardial infarction (n. 0), need for ultrafiltration due to acute renal failure (n. 0), acute respiratory failure (n. 1), stroke (n. 0), or atrial fibrillation (15%) was very low as already evident in other published papers [11]. Compared with the control group the incidence of atrial fibrillation and necessity of ultrafiltration were statistically significantly lower. In frail patient this minimal incidence of common complications probably represents the most considerable advantage and gives them a shortening in hospital stay and a better quality life after operation.

In patients who received Livanova Perceval necessity for pacemaker implantation was extremely high (24%). This finding differs from other data reported in literature showing rates around 6 to 10% [12]. However, at follow-up examination three of the five patients who underwent implantation in the immediate postoperative time, were not dependent of the pacemaker anymore, so the exactly needing for pacemaker rate was 10%. In the remaining patients the disorder of the conduction system was transient, but it has been treated in an aggressive way considering the characteristics of the population. Usually we wait at least from 3 to 7 days before implanting patients with definitive PMK. In this particular population we decided to treat before in order to reduce ICU stay and force allurement. In our series the incidence of this complication could be related with the extension of decalcification that in Perceval cases should be not so deep and should avoid the intranular portion of aortic annulus as during conventional prosthesis implantation. It is possible that we implanted oversized prosthesis in some of this cases which represented the first phase of our experience. Going ahead we better understood how sizing the prosthesis and reducing the pressure of the balloon and this probably caused decreasing in AV blocks incidence. This topic represents the main problem regarding the introduction on this new prosthesis in our Center and represents the main limit of our study. It is very important to underline that all the Perceval cases enrolled are the first series of patients treated by suture less aortic valve implantation at our center and part of our learning curve. Next data should be mandatory to clarify this aspect.

Analyzing the follow-up survival curves, there were no statistically significant differences between the two groups. It was also noted an improvement in the mean functional class. The rate of re-hospitalization for cardiac causes did not show statistically significant differences between the two groups. This suggests that the overall survival largely depends on fatal event in the early stage.

At 36 months freedom from adverse events, defined as association of mortality, need for re-hospitalization, thromboembolic and bleeding events, endocarditis, need for re-operation or paravalvular leak, was 85.7% in Group 1 vs. 75.2% in Group 2.

The scientific community is wondering about which should be the ideal patient that might be treated with a suture less prosthesis [13]. Based on our study, this prosthesis represents a safe and effective solution in patients with an increased operative risk, ensuring a lower incidence of postoperative complications, except for the need for pacemaker implantation, and a remote satisfactory survival, characterized by a good functional status and a low rate of adverse events.

D'Onofrio et al., compared suture less prosthesis to TAVI in high-risk subjects. In this study they observed same results in terms of mortality and peri-operative morbidity, with a lower incidence of paravalvular leak which remains one of the most frequent complications of transcatheter aortic valve prostheses [7]. In the postoperative period the presence of paravalvular leak is related to worse long-term survival [14] and for this reason it is an occurrence that must always be avoided.

Finally, in our study, patients treated with suture less valve received a bigger prosthesis than those underwent conventional aortic valve replacement. This option, in combination with structural characteristics of the prosthesis, allows larger effective orifice area thus the Sorin Perceval S can be an excellent choice in managing patients with small aortic annulus avoiding dangerous mismatch [15].

Due to the greater ease of implant, the suture less prosthesis can be effectively used in minimally invasive surgery. Santarpino et al., showed a better outcome in patients undergoing aortic valve replacement with suture less prosthesis using minimally invasive access, compared to those treated with the same access, but with conventional prosthesis [16].

Limitation of the study first of all is the low sample size that in some cases prevented to identify statistically significant differences between the two groups although the variables appear to support the SAVR group, secondly the design of the study which is not randomized and neither prospective. Regarding the small number of patients propensity score matching analysis was not possible. Next data should be mandatory.

In conclusion the Livanova Perceval™ suture less prosthesis is safe and effective and giving these reasons it may be proposed

in management of frail elderly patients affected by severe calcific aortic valve stenosis. A meticulous prosthesis sizing is mandatory in order to avoid damaging of conduction system.

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Cite this article

Russo M, Del Forno B, Saitto G, Gislao V, Bassano C, et al. (2016) Livanova Perceval Prosthesis to Treat Elderly Frail Patients: Immediate and Short-Term Results. Ann Cardiovasc Dis 1(2): 1011.