Original article

Similar outcome of tricuspid valve repair and replacement for isolated tricuspid infective endocarditis

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Aims **To compare early and late mortality of acute isolated tricuspid valve infective endocarditis (TVIE) treated with valve repair or replacement.**

Methods **Patients who were surgically treated for TVIE from 1983 to 2018 were retrieved from the Italian Registry for Surgical Treatment of Valve and Prosthesis Infective Endocarditis. All the patients were followed up by means of phone interview or calling patient referral physicians or cardiologists. Kaplan–Meier method was used to assess late survival and survival free from TVIE recurrence with log-rank test for univariate comparison. The primary end points were early mortality (30 days after surgery) and long-term survival free from TVIE recurrence.**

Results **A total of 4084 patients were included in the registry. Among them, 149 patients were included in the study. Overall, 77 (51.7%) underwent TV repair and 72 (48.3%) TV replacement. Early mortality was 9% (13 patients). Expected early mortality according to EndoSCORE was 12%. The TV repair showed lower mortality and major complication rate (7% and 16%), compared with TV replacement (11% and 25%), but statistical significance was not reached. Median follow-up was 19.1 years (14.3–23.8). Late deaths were 30 and IE recurrences were 5. No difference in cardiac survival free from IE was found between the two groups after 20 years (80 ± 6% Repair Group vs 59 ± 13% Replacement Group, $P = 0.3$).**

Conclusions **Overall results indicate that once surgically addressed, TVIE has a low recurrence rate and excellent survival, apparently regardless of the type of surgery used to treat it.**

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Keywords: tricuspid valve, endocarditis, tricuspid valve repair, tricuspid valve replacement

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Introduction

Acute infective endocarditis (IE) is becoming a more common entity that cardiac surgeons have to face.[1–3] Besides left-sided valvular infections, also right-sided valvular infections are increasing in prevalence (up to 12%),[4,5] probably due to an augmented number of cardiac implantable devices and of adults treated for congenital conditions;[3,6] moreover an increase in injectable-vein drug use (IVDU) has been documented.[7] Despite a different medical presentation of the two conditions, the mortality is similar.[8]

Among right-sided valvular infections the tricuspid valve (TV) is involved in 90% of cases.[9] Nevertheless, medical treatment of TV IE (TVIE) has a high rate of success, and surgery is indicated in 10–20% of patients.[10] Surgical treatment of TVIE includes valvectomy (which is performed less and less commonly[11] and associated with an increased mortality),[12] replacement and repair. Given the rarity of the procedure, few reports have addressed the optimal surgical treatment of TVIE, and most of them have short- to medium-term follow-up[10,12] or come from a previous era.[13] The aim of this study is to retrieve information from the National Registry for Surgical Treatment of Valve and Prosthesis Infective Endocarditis[11] to compare early and very long-term results of patients undergoing either repair of replacement of TV in a setting of TVIE.

Methods

Study population

The **I**talia**N** Registry **F**or surgical tr**E**atment of valve and prosthesis infe**C**tive endocardi**T**is (INFECT-REGISTRY) includes 4084 patients from February 1979 to January 2018, with 21 centers actively participating. The Registry is endorsed by the Italian Society for Cardiac Surgery (SICCH) with the Italian Group of Research for Outcome in Cardiac Surgery (GIROC). The ethical committee approved the study with protocol number 0009040 on 29/1/2015.

From 1983 to 2018, isolated acute TVIE was surgically treated in 157 out of 4069 (3.8%) patients, with 142 (90%) cases of native tricuspid regurgitation (TR), 7 (5%) of stenosis and regurgitation (TSR), and 8 (5%) of tricuspid prosthesis endocarditis.[11] Excluding the latter group, 149 patients with native TVIE were included, 77 had valve repair (Repair Group) and 72 replacement (Replacement Group). No patients underwent valvectomy in our experience.

Definition of terms and end points

All the variables collected in the dataset were defined according to EuroSCORE.[9] The primary end points were early mortality, defined as death within 30 days after surgery due to any cause, and long-term survival free from TVIE recurrence.

The secondary end points were long-term survival, 30-day mortality, and major complications (death, acute kidney injury, acute respiratory failure, multiorgan failure, sepsis, major bleeding, stroke, embolisms other than stroke, atrioventricular block needing PMK, acute myocardial infarction, malignant ventricular arrhythmias, low output syndrome). Moreover, observed/expected mortality ratio was reported using the EndoSCORE.[14]

Follow-up

All the patients were followed up by means of phone interview or calling patient referral physicians or cardiologists. Follow-up ended in March 2018; median follow-up was 19.1 years (14.3–23.8). Seven patients were lost at follow-up (11%).

Statistics

Normal distribution of continuous variables was assessed using the Kolmogorov–Smirnov test. Normally distributed variables are reported as mean and standard deviation; conversely nonnormally distributed variables are reported as median and quartiles. Pairwise comparison was performed with *T*-test or Mann–Whitney *U*-test in case of continuous variables and chi-square with Fisher exact test in case of categorical variables. The Kaplan–Meier Method was used to assess late survival and survival free from TVIE recurrence with log-rank test for univariate comparison. SPSS software (vers. 24, IBM Corporation, USA) and R-studio version 1.1.463 (2009–2018) were used to perform statistical analyses. $P < 0.05$ was considered as the threshold for statistical significance.

Results

Clinical profile and operative data

Mean age was 47 ± 17 years and 24% were females. *Staphylococcus aureus* was the most common pathogen (50%), followed by Streptococci (14%), Staphylococcus other than aureus (9%), Enterococcus (1%), Mycotic (1%), and other pathogens (3%). In 13% of the subjects, either blood cultures or specimen were negative, and in 8% of the patients the datum was missing. Regarding patient profiles, 37% of the population had IVDU, 22% had pacemaker/implantable cardioverter defibrillator PMK/ICD leads, 1% had vascular access for dialysis, and in the remaining cases the cause was unknown.

All the patients underwent surgery via median sternotomy. The TV repair was performed in 77 cases, starting from 1991 to 2018, with a significant reduction in prevalence across the periods (79% 1991–2000, 56% 2001–2010; 45% 2011–2018, $P = 0.012$). Likewise, TV was replaced in all cases in the first period, from 1983 to 1990, whereas in the last period it was chosen as a strategy in roughly half of the cases (Fig. 1 supplementary, http://links.lww.com/JCM/A447).

Among 77 patients undergoing TV repair, 22 (28.6%) had vegetectomy, 2 (2.6%) vegetectomy and reconstruction with patch, 37 (48.1%) vegetectomy and annuloplasty, 3 (3.9%) vegetectomy, patch reconstruction and

annuloplasty, 10 (13%) bicuspidalization, and 3 (3.9%) unknown. The types of conservative procedures used across different periods of the time-lapse of the study are reported in the supplementary Fig. 2, http://links.lww.com/JCM/A448; no difference was found ($P = 0.101$).

Among 72 patients undergoing TV replacement, 46 (63.9%) had a bioprosthesis, 13 (18%) a mechanical prosthesis and in 13 (18%) data are missing.

The type of implanted prosthesis across the time changed significantly ($P < 0.001$), with mechanical ones mainly used in the first periods and bioprostheses mostly afterwards (Fig. 3 supplementary, http://links.lww.com/JCM/A449).

Table 1 summarizes differences between the two groups.

Early outcome

Early mortality was 9% (13 patients). Expected mortality according to EndoSCORE[14] was 12% with O/E ratio 0.75. The 30-day major complications rate was 20% (30 patients). TV repair showed lower mortality and major complication rate (7% and 16%), compared with TV replacement (11% and 25%), but statistical significance

Table 1 Pre and operative data

	Overall $N = 149$	Repair Group $N = 77$	Replacement Group $N = 72$	*P*-value
Age (years)	47 ± 17	49 ± 17	44 ± 15	0.089
Female/male	36/113	62/15	51/21	0.185
TV disease				
TR	142 (90%)	73 (95%)	69 (96%)	0.368
TSR	7 (5%)	4 (5%)	3 (4%)	
Active endocarditis	115 (77%)	62 (81%)	53 (74%)	0.325
Source of infection				0.123
IVDU	59 (37%)	25 (33%)	34 (47%)	
PMK/ICD leads	32 (22%)	21 (27%)	15 (11%)	
Vascular access for dialysis	2 (1%)	2 (3%)	0	
Unknown	56 (37%)	29 (38%)	27 (38%)	
LVEF (%)	54 ± 9	54 ± 10	55 ± 8	0.295
SB hypertension	39 (26%)	24 (31%)	15 (21%)	0.152
Diabetes	11 (7%)	9 (12%)	2 (3%)	0.079
Obesity	10 (7%)	5 (7%)	5 (7%)	1.000
COPD	14 (9%)	7 (9%)	7 (10%)	1.000
Previous stroke	3 (2%)	0 (2%)	3 (4%)	0.110
Peripheral vasculopathy	4 (3%)	4 (5%)	0	0.121
Heart failure	18 (12%)	9 (12%)	9 (13%)	1.000
Shock	7 (5%)	3 (4%)	4 (6%)	0.712
CRF	15 (10%)	10 (13%)	5 (7%)	0.221
Cirrhosis	6 (4%)	2 (3%)	4 (6%)	0.430
Abscess	7 (5%)	2 (3%)	5 (7%)	0.264
Vegetations	81 (54%)	37 (48%)	44 (61%)	0.110
Leaflet perforation	12 (8%)	6 (8%)	6 (8%)	1.000
Blood/specimen bacteria or fungal				0.115
Staphylococcus aureus	74 (50%)	36 (47%)	38 (53%)	
Streptococci	21 (14%)	9 (12%)	12 (17%)	
Sthaphyloccus other than aureus	13 (9%)	10 (13%)	3 (4%)	
Enterococcus	2 (1%)	1 (1%)	1 (1%)	
Mycotic	2 (1%)	2 (3%)	0	
Pseudomonas	1 (0.6%)	0	1 (1%)	
Others	4 (3%)	3 (4%)	1 (1%)	
Negative blood culture or specimen	20 (13%)	7 (9%)	13 (18%)	
Missing data	12 (8%)	9 (12%)	3 (4%)	
Surgery				N/E
TV replacement	–	–		
with bioprosthesis	–	–	46 (64%)	
with mechanical prosthesis	–	–	13 (18%)	
missing	–	–	13 (8%)	
TV repair				N/E
Vegetectomy	–	22 (29%)	–	
Vegetectomy + Patch	–	2 (3%)	–	
Vegetectomy + Annuloplasty	–	37 (48%)	–	
Vegetectomy + Patch + Annuloplasty	–	3 (4%)	–	
Bicuspidalization	–	10 (13%)	–	
Unknown	–	3 (4%)	–	
CPB time (minutes)	72 (57-85)	71 (52–83)	74 (62–87)	0.145
Cross-clamping time (minutes)	45 (38–62)	44 (30–56)	48 (41–67)	0.091
EndoSCORE[14]%	12 (7–16)	10 (6–17)	12 (7–16)	0.818

TR, tricuspid regurgitation; TSR, tricuspid steno-regurgitation; IVDU, intravenous drug use; PMK/ICD, pacemaker/implantable cardioverter defibrillator; IE, infective endocarditis; LVEF, left ventricular ejection fraction; SB, systolic blood; COPD, chronic obstructive pulmonary disease; CRF, chronic renal failure; TV, tricuspid valve; TA, tricuspid annuloplasty; CPB, cardio-pulmonary.

Table 2 Early outcomes

	Overall $N=149$	Repair Group $N=77$	Replacement Group $N=72$	*P*-value
Deaths	13 (9%)	5 (7%)	8 (11%)	0.318
Stroke	1 (1%)	1 (1%)	0	1.000
Embolisms other than stroke	3 (3%)	1 (1%)	3 (4%)	0.354
Ventricular arrhythmias	1 (1%)	1 (1%)	1 (1%)	1.000
Postoperative AV block needing PMK	1 (0.7%)	0	1 (1%)	0.483
Low output syndrome	7 (5%)	2 (3%)	5 (7%)	0.264
IABP	3 (2%)	2 (3%)	1 (1%)	0.600
ECLS	2 (1%)	1 (1%)	1 (1%)	1.000
Multiorgan failure	7 (5%)	3 (4%)	4 (6%)	0.712
Respiratory failure	4 (3%)	1 (1%)	3 (4%)	0.354
Acute kidney injury	4 (3%)	3 (4%)	1 (1%)	0.621
Sepsis	8 (5%)	2 (3%)	6 (8%)	0.156
Major complications	30 (20%)	12 (16%)	18 (25%)	0.152

AV, atrio-ventricolar; IABP, intra-aortic balloon pump; ECLS, extracorporeal life support.

was not reached. Regarding perioperative morbidity, one-fourth of the patients experienced major complications, but, interestingly, event rates related to active infection (sepsis), or to acute cardiac as well as renal failure, were low (Table 2).

Late outcome

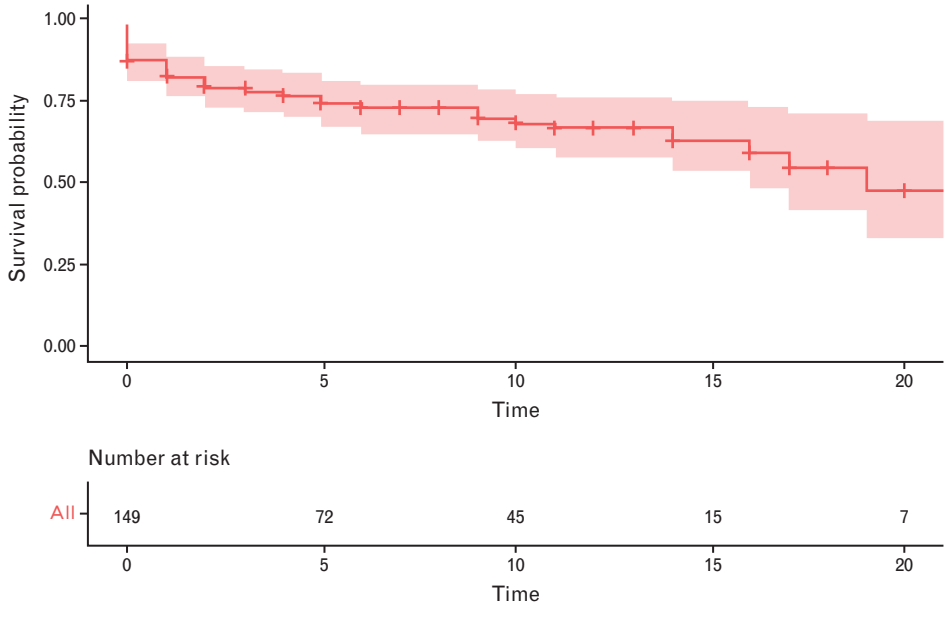
Survival at 5, 10, and 20 years was 74 ± 4%, 69 ± 5% and 48 ± 9%, respectively (Fig. 1). No difference was found between repair and replacement after 20 years (47 ± 13% Repair Group vs 51 ± 12% Replacement Group, $P=0.78$; Fig. 2).

At follow-up deaths cardiac-related were 13, IE relapse on TV were 5, with 4 deaths (2 cases among patients with bioprosthesis, 3 cases having TV repaired). Cardiac survival-free from IE relapse at 5, 10 and 20 years was 86% ± 3%, 81 ± 4% and 69 ± 8%, respectively (Fig. 3). No difference was found between the two groups after 20 years (80 ± 6% Repair Group vs 59 ± 13% Replacement Group, $P=0.35$; Fig. 4).

Discussion

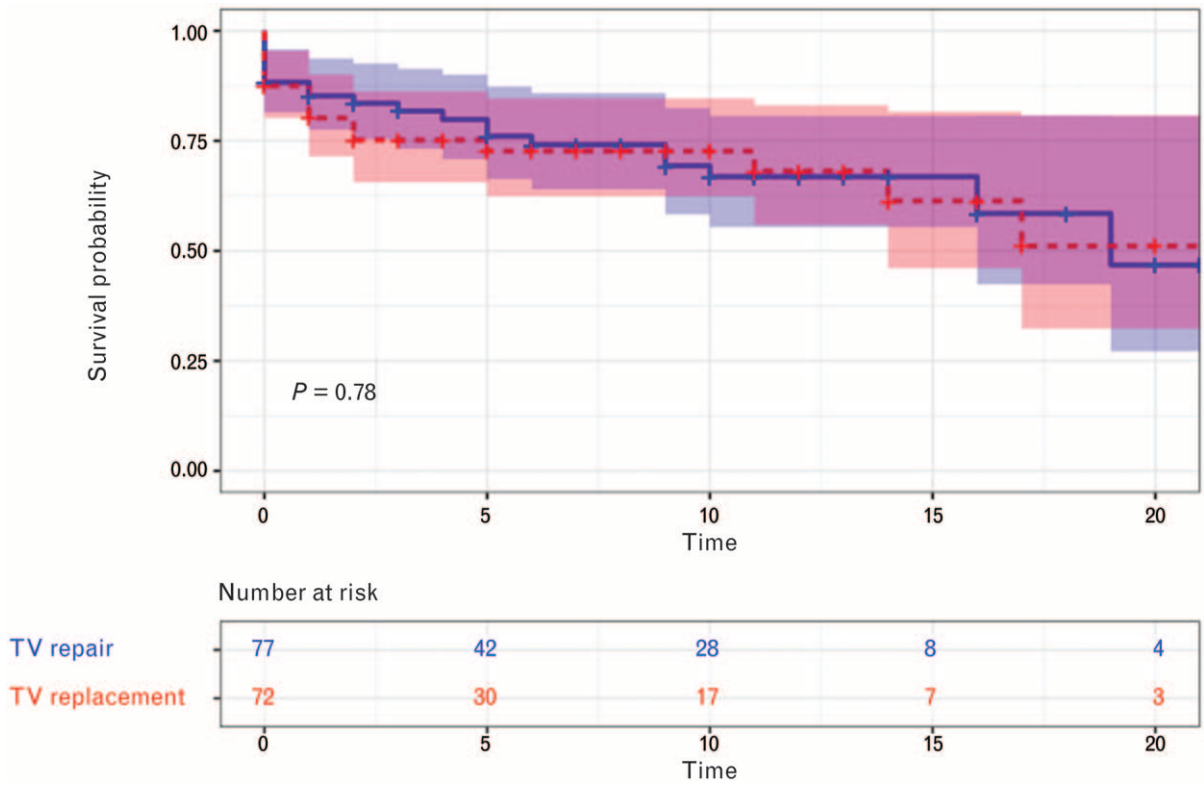
IE is a very dangerous and potentially deadly infection of the cardiac valve.[15] Right IE represents approximately 5–10% of all IE cases[16] and its incidence has been increasing in recent years,[4] very likely because of longer life expectancy of patients with intracardiac devices, congenital disease[3,6] and intravenous drug addiction.[7] Moreover, the virulence of IE is increasing, probably due to the etiological agent (*S. aureus* is the causative agent in 60–90% of cases) and the fast spreading of antibiotic resistance.[17] Generally predictors of poor outcome in IE are related to patient characteristics (older age, prosthetic valve, diabetes mellitus and comorbidity), clinical complications (heart and kidney failure, brain hemorrhage, ischemic stroke, and septic shock), infective agent and finally echocardiogram findings (periannular invasion, pulmonary hypertension, large vegetation, severe prosthetic valve dysfunction, signs of elevated diastolic pressure, etc.). Fever, multiple septic pulmonary emboli and bacteremia, associated with chest pain and caught or hemoptysis, are characteristic signs of right-sided IE. Also we can find paradoxical embolism when left-sided IE is associated with patent foramen ovale. Anyway, given the high response to medical therapy, according to ESC Guidelines[15] surgery is limited to a few

Fig. 1



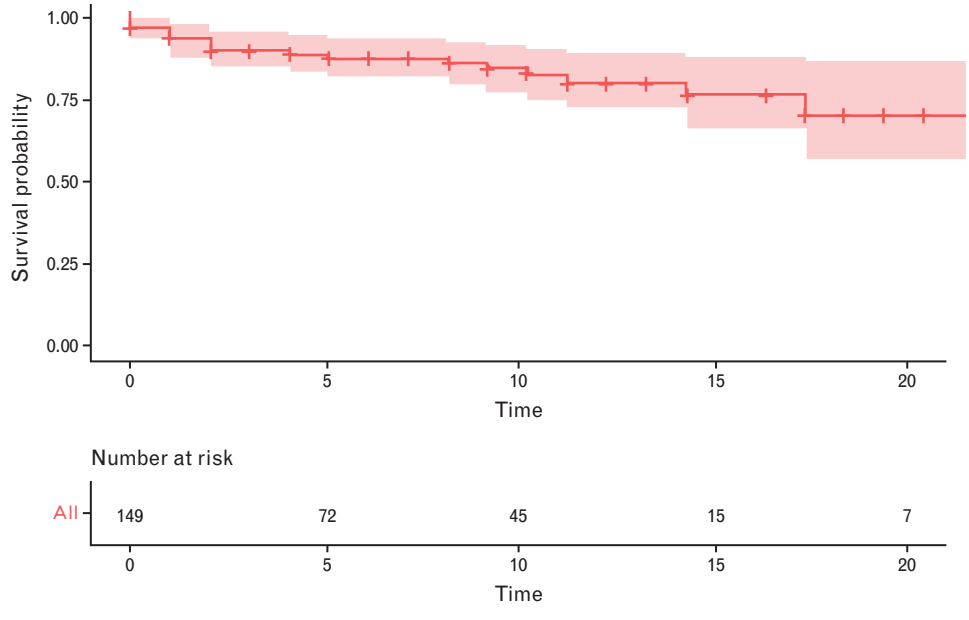
Twenty-year survival of overall cohort; 95% confidence limits were reported.

Fig. 2



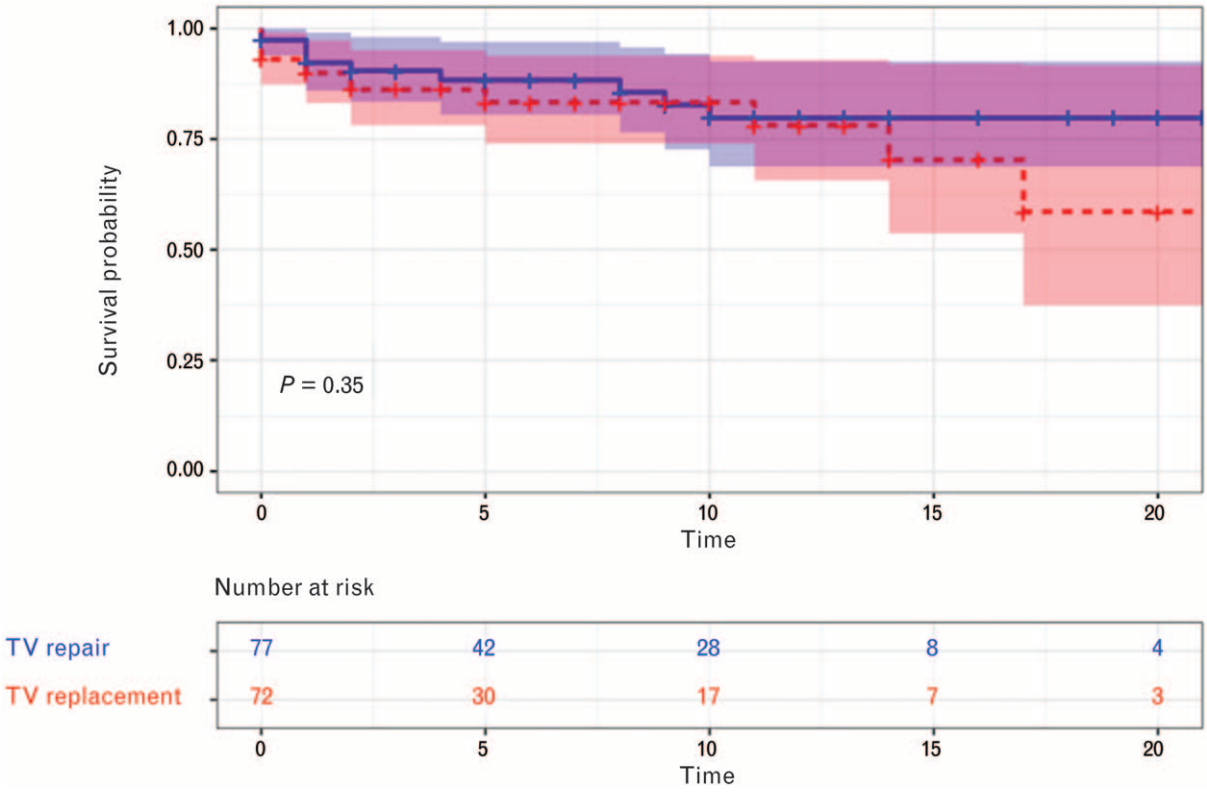
Twenty-year survival stratified by tricuspid valve repair (blue line) and replacement (red line); 95% confidence limits were reported.

Fig. 3



Twenty-year cardiac survival free from infective endocarditis relapse of overall cohort; 95% confidence limits were reported.

Fig. 4



Twenty-year cardiac survival free from infective endocarditis relapse stratified by tricuspid valve (TV) repair (blue line) and replacement (red line); 95% confidence limits were reported.

symptomatic cases: Class IIa, Level C in persistent valve vegetation >20 mm after recurrent pulmonary embolism (with or without concomitant right heart failure), right heart failure (secondary to severe TR) and/or persistent infective status or bacteremia for >7 days despite adequate antimicrobial therapy.

Our study is a retrospective multicenter study, the result of Italian experience on isolated TVIE surgically treated. The data were extrapolated from the Italian Registry for Surgical Treatment of Valve and Prosthesis Infective Endocarditis.[11] TVIE represents around 4% of the total IE of the Registry cases, as already reported in our previous report and by others.[2,15,18–20] According to EndoSCORE,[14] expected mortality was 12%, so our O/E ratio was 0.75. Early outcome of TV repair shows lower mortality and major complication rates compared with TV replacement; also sepsis or acute cardiac as well as renal failure was low.

In our series, *S. aureus* was the most common pathogen, followed by Streptococci, Staphylococcus other than aureus, Enterococcus, Mycotic, and other pathogens. Specifically, the prevalence of *S. aureus* is significantly higher in IVDU patients than in non-IVDU patients. Regarding patient profiles, according to previous series published, the majority of the population were IVDU patients, following by intracardiac leads, and vascular access for dialysis; the cause was unknown in the remaining cases.

Removal of infected tissue (vegetation, perforated leaflet and abscesses) is the first goal of surgical treatment. Therefore, it could be sometimes necessary for the removal of all leaflets or a part of them, then proceeding to valve reconstruction[21] (autologous pericardium, neochordae, or bicuspidalization techniques). In our series, valve repair and valve replacement were considered. Cardiopulmonary bypass was used in all patients, with the maximum time of 60 min of aortic-cross-clamping time, just in case of complex reconstruction. We did not consider valvectomy, even though it is performed in more than 7% of surgical TVIEs in North America.[22] Slaughter *et al.*[12] show that in IVDU-associated TVIE, valvectomy is an independent predictor of operative mortality, and valve repair should be the preferred management for TV endocarditis degeneration whenever possible.

Nevertheless, the history of the surgical treatment of TVIE is not so linear. Indeed, among decades, the preferred surgical approach changed. Up to 1990, repair was rarely performed and the TV was replaced most of the time.[23] Afterwards, there was a switch in the trend and

surgeons started to adopt a more conservative approach.[24] In recent years, a balance was reached, so that TV replacement and repair were both used depending on the pathological-anatomical findings: in the case of complete destruction of tissue, TV replacement becomes mandatory, otherwise a repair is attempted especially in experienced centers.[25] The latter ones are advisable because TV repair in an endocarditis setting can be complex. First of all, despite the reluctance to use prosthetic materials, a ring prosthesis has been proven to be necessary for a good result.[26] Besides the ring, usually multiple techniques can be used to repair the infected valve, including chordal and leaflet reconstruction with pericardial patches.[27]

However, in accordance with others,[13] we did not find a significant statistical difference between TV repair and TV replacement. Despite a very long follow-up (up to 20 years), no difference in cardiac survival free from IE relapse was found between Repair Group vs Replacement Group. This is very likely due to the choice of the correct surgical approach for each TVIE condition. In half of cases, the presence of a highly destroyed valve forced surgeons to implant a prosthesis rather than try a complex valve reconstruction.

When a replacement is needed, the choice of the optimal prosthesis becomes of pivotal importance. Nevertheless, the debate on the best prosthesis choice is still active and ongoing.

In our series, most of the patients received a bioprosthesis which, although avoiding the patients' needing lifelong oral anticoagulation with its possible consequences, is highly prone to structural degeneration,[28] especially in young patients, such as those undertaking IVDU. Nevertheless, surgeons preferred to implant a bioprosthesis for different possible reasons:[29] higher prevalence of IVDU in recent years;[7] in our series, from 2011 to 2018, 29 out of 62 patients were drug abusers. Furthermore, newer advantages in the field of preservation technology,[30] eliminating for instance free aldehydes, reduced significantly the likelihood of prosthesis calcification, thereby improving their durability, even in younger patients.[29,30–32] Finally, with the increasing wave of enthusiasm for the improved percutaneous valve implantation, surgeons are more confident to implant a bioprosthesis even in a tricuspid position, foreseeing future percutaneous treatment.[33–35]

On the one hand, there are mechanical prostheses, potentially lasting a lifetime, but needing anticoagulant therapy, which may become potentially dangerous in a reluctant patient such as an IVDU patient. In fact, in our series, mechanical prostheses were chosen only in 18% of cases, mainly in the first period, and none of them was an IVDU patient.

In our report, no difference in operative mortality was found between biological and mechanical prostheses, as other authors reported.[29,36,37]

Interestingly, new devices have been proposed to treat TVIE with good results.[16] Therefore, as Veve *et al.*[38] suggested, percutaneous mechanical aspiration of TV vegetation could be considered in young IVDU patients as bridge to surgery during addiction rehabilitation.

Another important risk factor in right IE, after IVDU, is an implantable electronic device.[39] It is a severe event associated with high mortality.[40] It is often caused by insertion site infection of hardware, but it is a distinct separate disease, according to the Guidelines.[1] Local device infection is limited to the pocket of the generator device; it manifests with local edema, wound dehiscence and purulent drainage. Cardiac device-related IE is defined as 'an infection extending to the electrode leads, cardiac valve leaflets or endocardial surface'.[15] In our series, such a condition represented the second cause of right IE and it was found to be a negative predictor for late survival. This might also depend on the older age at which patients are usually implanted with cardiac devices, underlying an initial worse clinical and cardiac status.

In recent years, the idea of IE evolved from a single specialist pathology to a disease needing a multidisciplinary approach. The severity of disease is derived from the number and degree of involvement of other organs, the bacteria and the presence of complications. The final diagnosis and the following strategy, either surgical or conservative, should be performed by an Endocarditis Team.[41,42]

A more aggressive and early surgical approach has been proved to have better outcomes, with a significant reduction in early mortality. As aforementioned, long-term outcomes in our series showed good results in accordance with published data. Recurrences of IE were few, but with an extremely poor prognosis.

According to guidelines and other series[1,43] our analysis showed that age, mycotic TVIE, IVDU, reoperation for an infected prosthetic valve, and presence of right intracardiac device are negative predictors of an unfavorable outcome.

Study limitations

Study limitations are connected with patient population and the retrospective nature of the data analysis. This is a 25-year study evaluation; in this long period the surgical and medical expertise and quality in patient care have increased. Likewise, guidelines have changed. Hence, we could not cite all ESC guidelines across the period, so we decided to cite just the current one. Clinical scenarios and type of surgical and medical approaches showed remarkable variability also for new technologies introduction, like the percutaneous aspiration system, antibiotic therapy in order for antimicrobial resistance and most diffuse culture of endocarditis team approach. Moreover, given the retrospective nature of the study, some important information is missing such as surgical indications, timing of surgery, and biological prosthesis status at follow-up.

Conclusion

In conclusion, TVIE represents today a well known and challenging pathology. Preoperative patient profiles and disease features may indicate patients at higher risk. Overall results indicate that once surgically addressed, TVIE has a low recurrence rate and excellent survival, apparently regardless of the type of surgery used to treat it. Surgical strategy should be tailored on valve condition.

Conflicts of interest

There are no conflicts of interest.

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