## PROPOSTA DI LAVORO SCIENTIFICO

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Titolo dello studio: Mitral valve replacement or repair for Post-Actinic Mitral valve disease.

Tipo Di Studio:

- 1. Retrospettivo
- 2. Prospettico Non Randomizzato
- 3. Trial
- 4. Registro
- 5. Meta-Analisi Systematic Review

Ho letto e approvo le regole di authorship del GIROC: SI NO

Sono consapevole che in caso di accettazione, mi occuperò personalmente dell'approvazione del C.E presso il mio Centro: **SI** NO

Premessa con referenze (max 15 righe, ref. escluse):

Valvular disease happen in up to 80% of irradiate patients [1] and in up to 26% there is a marked calcification of the aortomitral curtain [2]. Accordingly, valve replacement might be preferable to valve repair when considering long-term cardiovascular outcomes [3].

There are few studies in the literature discussing the results of mitral valve surgery because of post-actinic disease, with limited sample. Therefore, there is no evidence if mitral valve repair or replacement (either with biological or mechanical valve) is better. Eoin Donnellan et al. [4] presented a sample of 146 patients who underwent mitral valve surgery after a median time of 17 years and showed that older age, higher STS score, coronary disease, REDO surgery and female sex were associated to higher mortality. Still, they could not infer anything on the best fitting type of surgery. Juan Crestanello et al. [3] instead focused on the repair of the mitral valve, showing that Overall survival, freedom from cardiac death, and freedom from valve reoperation or cardiac transplantation at 5 years for early survivors was 66%, 85%, and 88%, respectively. It is unclear if the radiation damage keeps ruining the mitral valve. In such a scenario, mitral valve replacement might be the best option as the advantages of mitral valve repair might be lost [5].

- [1] Jaworski C, Mariani JA, Wheeler G, Kaye DM. Cardiac complications of thoracic irradiation. J Am Coll Cardiol. 2013;61:2319–2328. doi: 10.1016/j.jacc.2013.01.090
- [2] P.A. Heidenreich, S.L. Hancock, B.K. Lee, C.S. Mariscal, I. SchnittgerAsymptomatic cardiac disease following mediastinal irradiation J Am Coll Cardiol, 42 (2003), pp. 743-749
- [3] J.A. Crestanello, C.G. McGregor, G.K. Danielson, et al.Mitral and tricuspid valve repair in patients with previous mediastinal radiation therapy Ann Thorac Surg, 78 (2004), pp. 826-831 discussion 826–31
- [4] Donnellan E, Alashi A, Johnston DR, Gillinov AM, Pettersson GB, Svensson LG, Griffin BP, Desai MY. Outcomes of Patients With Mediastinal Radiation-Associated Mitral Valve Disease Undergoing Cardiac Surgery. Circulation. 2019 Oct 8;140(15):1288-1290. doi:
- 10.1161/CIRCULATIONAHA.119.040546. Epub 2019 Oct 7. PMID: 31589484.
- [5] Pahwa S, Crestanello J, Bernabei A, Schaff H, Dearani J, Lahr B, Greason K. Mitral Valve Repair vs Replacement in Patients with Previous Mediastinal Irradiation. Semin Thorac Cardiovasc Surg. 2021 Sep 8:S1043-0679(21)00410-X. doi: 10.1053/j.semtcvs.2021.09.002. Epub ahead of print. PMID: 34508812.

## Scopo Dello Studio (max 10 righe):

We propose a retrospective study to evaluate the difference among patient with post-actinic mitral valve disease treated with mitral valve repair or mitral valve replacement with biological prosthesis or mitral valve replacement with mechanical prosthesis.

#### **End-Points Primari:**

Mortality and early post operative outcomes

### **End-Points Secondari:**

long-term follow up (mortality and mitral events, defined as: mitral re-intervention, thromboembolic events, endocarditis, paravalvular leaks or at least moderate residual mitral regurgitation)

# Tempi previsti di arruolamento (in mesi):

## Cenni statistici:

Retrospective multicenter study in Italian Centers recollecting data of patient treated in the last 10 years.

Univariate and multivariate analysis will be performed to determine relationships between variables and in-hospital mortality, aortic events, and follow-up mortality.

#### **INCLUSION CRITERIA**

- Age ≥ 18 years old
- Post actinic mitral valve disease

#### **EXCLUSION CRITERIA**

• Age < 18 years

## Punti di forza:

Evaluation of the best type of surgery on the mitral valve Large sample

## Eventuali limiti:

Retrospective study

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# Fondi/Costi previsti:

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Eventuali sponsorizzazioni esterne (pubbliche o private):

Eventuale numerosità del campione (se prospettico):

Numero minimo di pazienti da arruolare per Centro per partecipare: 20 subjects per center