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2. Case studies – with patient consent

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POST-STERNOTOMY MEDIASTINITIS: A MEDICOECONOMIC STUDY COMPARING TWO PREVENTIVE STRATEGIES IN CARDIAC SURGERY

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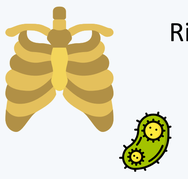
BACKGROUND AND IMPORTANCE



Open heart surgery

Risk of postoperative mediastinitis = serious sternal wound infection

→ *Causing excess mortality and prolonged hospitalizations*

The risk factors (RF) found in the literature are :

- Coronary artery bypass with bilateral internal mammary grafting (BIMA)
- Insulin-dependant diabetes / obesity / chronic obstructive pulmonary disease (COPD) / history of mediastinal radiotherapy / active smoking

Incidence of postoperative mediastinitis		
Marie Lannelongue hospital (HML) : 4,2% (2020)	>	Literature up to 3%/year

COLLATAMPG®

- ✓ **Two preventive strategies** are considered :
  - Insertion during sternal closure of the **COLLATAMPG®** (Serb), bioabsorbable bovine collagen implant impregnated with gentamicin
  - Immediate postoperative application of negative pressure therapy to the sternal wound with the **PICO®7** system (Smith & Nephew)

PICO®7

AIM AND OBJECTIVES

① **Compare the cost-effectiveness** of these two preventive strategies

② **Evaluate the impact** on **length of stay** and **antibiotic (ATB) consumption**

MATERIALS AND METHODS

Cost-effectiveness analysis

- *Monocentric – 3 arms*
  - ***1 retrospective control arm –*** *standard sternal dressing = MEPORE® (Molnlycke)*
    - → *01/07/2019 – 30/09/2019*
    - → *Identification of HML patients on the national EPICARD database*
  - ***2 prospective intervention arms –*** *COLLATAMPG® and PICO®7*
    - → *23/11/2020 – 19/02/2021*
- *Comparaison of COLLATAMPG® and PICO®7 arm versus control arm*

COST STUDY

- ✓ Calculation of **postoperative hospital costs** for each strategy
  - **Consumed resources evaluated by microcosting**
    - → Medical device (MD) / ATB → *management software (Qualiac®)*
  - **Hospital stays + reoperations evaluated by reference cost**
    - → Cost of a day in care unit and intensive care unit at HML
    - → Operating room hourly rate at HML

Calculation of the **incremental cost effectiveness ratio (ICER)**

PATIENT INCLUSION AND EXCLUSION CRITERIA

- ✓ **Inclusion : open heart surgery + at least one postoperative mediastinitis RF** (coronary artery bypass with BIMA, BMI≥30kg/m², treated diabetes, active smoker, treated COPD, history of mediastinal radiotherapy)
- ✓ **Exclusion : deaths from non-infectious causes** during the study period

EFFECTIVENESS STUDY

- ✓ **Primary endpoint = incidence of mediastinitis at 1 month after surgery (M1)**
  - Mediastinitis = surgical revision for deep infection of the surgical site with positive bacteriological samples (bone, mediastinal fluid)
  - Inclusion of superficial infections requiring surgical revision and prolonged hospitalization for antibiotic therapy
- ✓ **Secondary endpoints** → *Medical record (Hopital Manager®)*
  - Length of stay (conventional hospitalization / intensive care)
  - ATB consumption

RESULTS

POPULATION

	Control	COLLATAMPG®	PICO®7
Number of patients	48	25	9
Mean age (years)	64 [31;81]	65 [24;84]	60 [47;73]
Male-to-female ratio	7	5,3	3,5
Average number of RF	1,7	1,8	2,4*

** Statistically significant (p<0,05 – Chi² test)*

PRIMARY ENDPOINT
DIAGNOSIS OF MEDIASTINITIS AT M1

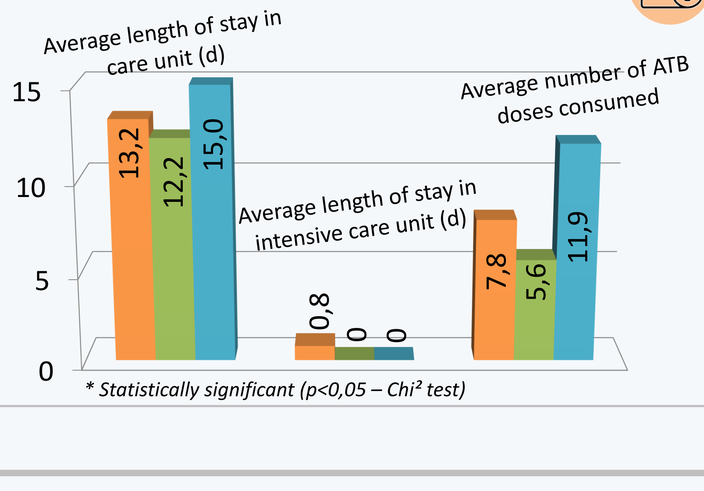
	Control	COLLATAMPG®	PICO®7
Number of mediastinitis	4	1	1
Number of reversed suspicions	0	2	0
Incidence of mediastinitis	8,3%	4,0%	11,1%

** Statistically significant (p<0,05 – Fisher test)*

⇒ **PICO®7 arm**

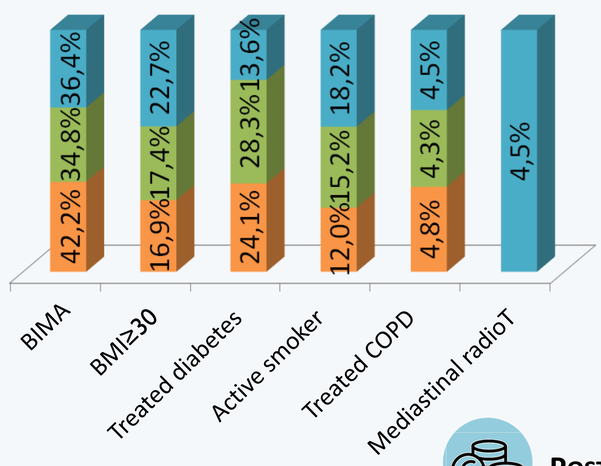
- Average application time = 4,7days
- 2 cases of air leak in patients with high BMI (>34kg/m²) making the system ineffective

SECONDARY ENDPOINTS

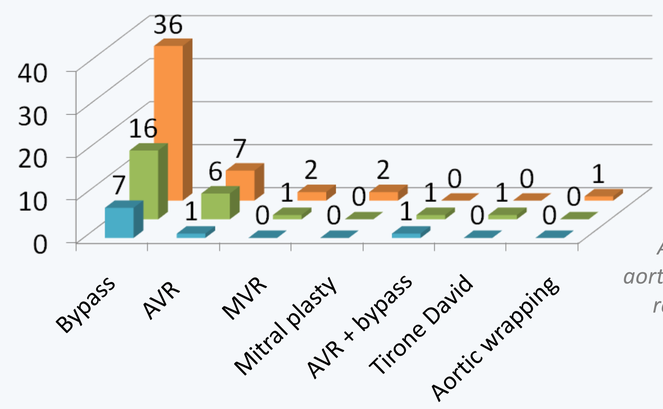


** Statistically significant (p<0,05 – Chi² test)*

DISTRIBUTION OF RF



NATURE OF INTERVENTIONS *(n=82)*



AVR/MVR = aortic/mitral valve replacement

POSTOPERATIVE HOSPITAL COSTS

CONTROL ARM			COLLATAMPG® ARM			PICO®7 ARM		
Hospital stay 12 238€ | ***95,2%***			Hospital stay 9 845€ | ***94,2%***			Hospital stay 12 105€ | ***98,7%***		
ATB 124€ | ***1,0%***	MD 0,4€ | ***<0,1%***	Surgical revision 497€ | ***3,8%***	ATB 8€ | ***0,1%***	MD 125€ | ***1,2%***	Surgical revision 472€ | ***4,5%***	ATB 38€ | ***0,3%***	MD 120€ | ***1,0%***	Surgical revision 864€ | ***6,6%***
12 860€/patient			**10 451€/patient**			**13 127€/patient**		

ICER = ΔCost/ΔIncidence

→ **ICER (COLLATAMPG® *vs* control) = 55 583€/mediastinitis avoided**

→ **ICER (PICO®7 *vs* control) = 9 616€/mediastinitis avoided**

CONCLUSION AND RELEVANCE

- ✓ **Comparaison of the two preventive strategies**
  - The difference in the incidence of mediastinitis is not significant (p > 0,05)
  - The ICER is positive for COLLATAMPG® and PICO®7 → **prevention reduces costs**
  - **Both strategies are more cost effective than standard sternal dressing**
  - **The ICER is in favor of COLLATAMPG®**
  - **PICO®7 arm** → the average number of RF is statistically higher (p < 0,05) and the observed leaks can be resolved

Problem of study power → Short study duration and low incidence of medistinitis

- ✓ **By supporting surgical teams in the evaluation of preventive strategies the hospital pharmacist contributes to optimize treatments at the best cost** ①

- ✓ **Impact on length of stay**
  - Not significant for COLLATAMPG® and PICO®7 (p > 0,05)
- ✓ **Impact on ATB consumption**
  - Not significant for COLLATAMPG® and PICO®7 (p > 0,05)

②

- ✓ **Perspectives**
  - Leakage problem of PICO®7 : addition of a RENASYS® (Smith & Nephew) sealing patch when there is a risk of leakage, under test → medico-economic impact to be re-evaluated with this parameter
  - Continue the study with a larger number of patients by extending the inlcusion period or expanding to other centers

Kowalewski M, Pawliszak W, Zaborowska ME et al. Gentamicin-collagen sponge reduces the risk of sternal wound infections following heart surgery. Meta-analysis. J Thorac Cardiovasc Surg. 2015;149:1631-40.

Hyldig N, Birke-Sorensen H, Kruse M et al. Meta-analysis of negative-pressure wound therapy for closed surgical incisions. BJS. 2016;103:477-86.