Archives of Cardiovascular Disease (2019) 112, 691—698

Available online at ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com/en

CLINICAL RESEARCH

Is the MitraClip® procedure profitable in a high-volume French hospital?

L'implantation d'un dispositif MitraClip® est-elle rentable dans un centre hospitalier français à haut volume?

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Received 25 April 2019; received in revised form 17 July 2019; accepted 22 July 2019
Available online 19 September 2019

KEYWORDS
Hospital costs;
Heart valve disease;
Mitral valve insufficiency

Summary
Background. — Mitral regurgitation is the second most frequent valvulopathy managed by surgery in Europe. For patients who have a contraindication to surgery or a high surgical risk, the percutaneous MitraClip® implantation procedure has emerged as a favourable alternative approach, but elevated procedural costs are a medicoeconomic concern.
Aim. — The objective of this study was to evaluate whether the MitraClip® procedure is profitable in a high-volume French hospital.
Methods. — Patients eligible for mitral valve repair with a MitraClip® device, and covered by the French National Health Service, were included retrospectively in this single-centre study between September 2016 and June 2018. Subgroups were considered based on medicoeconomic severity level. The study primary endpoint was the difference between hospital costs and revenues, calculated for each patient. Secondary endpoints included profit based on severity level, breakdown of costs and adverse events during hospitalization.
Results. — Twenty-two patients were included in the study. The mean hospital cost and revenue were €30,039 ± 2476 and €30,331 ± 2720 per patient, respectively, resulting in a profit of

Abbreviations: BMI, body mass index; GHM, Groupe Homogène des Malades (diagnosis-related group); ICU, intensive care unit; MR, mitral regurgitation.

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https://doi.org/10.1016/j.acvd.2019.07.002

€292 ± 2039 per patient. The total estimated profit was €6429 for the whole study period. The largest benefits were observed for patients assigned to the higher medicoeconomic severity levels (levels 2 and 3). Profit increased following a reduction in the device cost (€1136 ± 2415 per patient). The price of the device represented 78% of the total costs.
Conclusions. — Percutaneous MitraClip implantation is a financially neutral procedure for a French university hospital, but this depends on patient severity level.

MOTS CLÉS
Coût hospitaliers ;
Maladie des valves cardiaques ;
Insuffisance de la valve mitral

Résumé
Contexte. — L'insuffisance mitrale est la seconde valvulopathie la plus opérée en Europe. Pour les patients présentant une contre-indication à la chirurgie ou un risque chirurgical élevé, l'implantation percutanée du dispositif MitraClip® est une alternative dont les coûts élevés constituent une préoccupation médico-économique.
Objectif. — L'objectif était d'évaluer si la procédure MitraClip® est rentable dans un hôpital français.
Méthodes. — Les patients éligibles pour une réparation mitrale par MitraClip® et assurés par la sécurité sociale ont été inclus de façon rétrospective et monocentrique entre septembre 2016 et juin 2018. Des sous-groupes de sévérité ont été considérés. Le critère de jugement principal était la différence entre coûts hospitaliers et remboursement par patient. Les critères de jugement secondaires comprenaient le bénéfice par sous-groupe de sévérité; la distribution des coûts et les événements indésirables durant l'hospitalisation.
Résultats. — Vingt-deux patients ont été inclus dans l'étude. Par patient, le coût moyen de la procédure était de 30,039 ± 2476 € et le remboursement moyen de 30,331 ± 2720 €, donnant un bénéfice moyen de 292 ± 2039 €. Le gain total pour l'institution était de 6429 € pour la durée de l'étude. Les meilleurs profits étaient observés pour les patients des sous-groupes de sévérité 2 et 3. Le profit était plus important après la diminution du coût du dispositif (1136 ± 2415 € par patient). Le montant du dispositif représentait 78 % des coûts totaux.
Conclusions. — La procédure MitraClip® est peu rentable pour un hôpital français sauf en cas de sévérité des patients.

Background

Mitral regurgitation (MR) is the second valvulopathy, in terms of frequency, managed by surgery in Europe, just after calcified aortic stenosis [1]. Prevalence is about 1.7% in the general population, and reaches 9.3% in the elderly after 75 years [2]. The most frequent aetiology is degenerative valve disease, followed by rheumatic disease [2].

The standard of care for the treatment of severe MR is surgical repair or replacement of the mitral valve [3—5]. However, a significant proportion of patients do not undergo surgery, because they have severe co-morbidities and/or a high surgical risk. These patients are treated medically, especially those with left ventricular dysfunction, symptoms of heart failure or secondary MR [6,7].

The emergence of percutaneous techniques, such as transcatheter aortic valve replacement or, more recently, balloon commissurotomy for mitral stenosis, has revolutionized the treatment of valvulopathies in patients who cannot undergo conventional surgery. The surgical ''*double-orifice*'' technique, originally proposed by Alfieri et al., has served as proof-of-concept for the development of the transcatheter MitraClip® device (Abbott Vascular, Menlo Park, CA, USA) for the treatment of MR [8]. In the randomized Endovascular Valve Edge-to-Edge Repair Study (EVEREST II), the percutaneous approach with the MitraClip® device, when compared with conventional therapy, was associated with superior safety and similar improvement in functional class, despite more residual MR [9]. Current European and American guidelines recommend the MitraClip® procedure in patients with symptomatic severe degenerative (primary) MR despite optimal medical treatment (class of recommendation IIb and level of evidence B or C) [4,10]. For patients with severe secondary MR, the procedure is only supported by the European guidelines (class of recommendation IIb and level of evidence C).

The economic burden of MR is substantial in France, with a total annual cost of > €292 million for year 2009, including €192 million for medical therapy [11]. The MitraClip® procedure is expensive, and device implantation in elderly patients with co-morbidities is questionable for the society and the hospital. Yet, several cost-effectiveness studies based on extrapolation models suggest that the MitraClip® procedure is cost-effective over time compared with

conventional medical management in patients with severe MR [12—15].

In France, the French National Health Service has refunded the MitraClip® device since November 2016 for degenerative MR, in symptomatic patients who are not eligible for surgical repair after Heart Team evaluation. In 2018, the price of the device decreased from €24,054 to €21,000. The goal of this study was to perform a cost-revenue analysis for the MitraClip procedure in a high-volume French hospital.

Methods

Study population

Eligible patients were those scheduled to undergo MR repair with a MitraClip® device at the University Hospital of Nantes, France, after assessment of echocardiographic eligibility criteria and evaluation by a Heart Team composed of cardiologists, cardiothoracic surgeons and anaesthesiologists. Included patients had to be covered by the French National Health Service.

All consecutive eligible patients identified between November 2016 and June 2018 were included in the study retrospectively, and the clinical data were collected in a local database.

MitraClip® procedure

The MitraClip® device was introduced percutaneously via a transseptal approach under general anaesthesia, using fluoroscopy and transoesophageal echocardiographic guidance, as described elsewhere [9].

Systematic echocardiography was performed at the end of procedure and before hospital discharge to check for successful implantation and to evaluate residual MR.

Patient subgroups

Medicoeconomic data were collected from the French National Health Service and the Medical Program of Information Systems [Programme de médicalisation des systèmes d'information (PMSI)]. In accordance with the French medicoeconomic classification system by diagnosis-related groups [Groupe homogène de malades (GHM)], patients receiving a MitraClip® device (Codes 05K221 05K222, 05K223 and 05K224 from the 2016 French National Scale of Health Costs) were divided into four severity-level subgroups (from 1 to 4; 4 being the most severe level), depending mostly on medical background and in-hospital complications.

Cost-revenue analysis

For each patient, we calculated the total cost of the MitraClip® procedure, and compared it with the reimbursement received by the hospital. The costs were assessed using the 2016 French National Scale of Health Costs (available online at http://www.scansante.fr/applications/enc-mco), and were dependent on length of hospital stay and development of early complications.

Four different costs were considered, and totalled to provide a global cost per patient: (1) the clinical cost, which included all costs related to the hospitalization unit [intensive care unit (ICU) and/or standard unit]; (2) the medicotechnical cost, which included all costs related to the procedure, i.e. cost of operating room, standard laboratory and imaging (fluoroscopy; oesophageal echocardiography), remuneration of doctors and nurses during the procedure, and maintenance and depreciation costs of the equipment; (3) the logistical cost, which included medical costs (pharmacy, hygiene) and general costs (laundry, nourishment, administration, patient handling); and (4) the direct cost, which included the price of the device(s), medications and consumables.

The cost of medical devices and blood products, and the remuneration of doctors and nurses during the procedure were estimated for each patient using microcosting analysis.

The global revenues for the hospital were determined for each patient as the sum of three separate revenues: the standard reimbursement defined by the patient severity level; a supplement for patients monitored in an ICU or reanimation unit; and reimbursement of implanted devices.

Endpoints

The primary endpoint was the economic profit associated with the MitraClip® procedure. The profit was calculated for each patient as the difference between costs and revenues, and for the overall study patient population by multiplying by the number of patients.

The secondary endpoints were economic profit by severity level, and the breakdown of costs overall and by severity level. Hospital complications were also recorded.

Statistical analysis

Continuous variables are reported using means ± standard deviations, and were compared using the *t* test. Comparisons between groups were performed using the analysis of variance (ANOVA) test.

Statistical analyses were performed with STATPLUS® version 6.7.1.0 (AnalystSoft, Walnut, CA, USA).

Results

Study population

Between September 2016 and June 2018, 22 MitraClip® procedures were reimbursed by the French National Health Service as degenerative MR ($n = 18$, 82%) or secondary MR (two ischaemic MR and two functional MR) supported by a research protocol ($n = 4$, 18%). Most of the time, the interventional procedure was performed because of frailty, high risk of reoperation and/or elevated Society of Thoracic Surgeons' score precluding conventional surgery.

Patient demographic and preoperative characteristics are presented in Table 1. The mean age was 83 ± 7 years, the mean left ventricular ejection fraction was 56 ± 12% and P2 mitral prolapse was present in 11 patients (50%). There was no patient in severity level 4 in the study. There was

Table 1 Demographic and preoperative characteristics.

	All patients	GHM severity level[a]			*P*
	(*n* = 22)	Level 1(*n* = 6)	Level 2(*n* = 8)	Level 3(*n* = 8)	
Male sex	15 (68)	4 (67)	4 (50)	7 (88)	0.3
Age (years)	83 ± 7	84 ± 6	82 ± 10	82 ± 4	0.78
BMI (kg/m^2)	24.7 ± 3.2	25.1 + 2.6	23.1 ± 2.9	25.8 ± 3.7	0.23
Smoker	8 (36)	3 (50)	3 (38)	2 (25)	0.66
Hypertension	17 (77)	4 (67)	7 (88)	6 (75)	0.68
Dyslipidaemia	10 (45)	3 (50)	2 (25)	5 (63)	0.34
Diabetes mellitus	7 (32)	1 (17)	1 (13)	5 (63)	0.07
Cardiovascular heredity	2 (9)	0 (0)	1 (13)	1 (13)	0.7
Atrial fibrillation	16 (73)	4 (67)	6 (75)	6 (75)	0.94
Permanent pacing	3 (14)	1 (17)	1 (13)	1 (13)	0.97
Coronary artery disease	8 (36)	3 (50)	1 (13)	4 (50)	0.24
Peripheral vascular disease	2 (9)	0 (0)	0 (0)	2 (25)	0.16
Chronic respiratory disease	6 (27)	3 (50)	1 (13)	2 (25)	0.32
Creatinine concentration (μmol/L)	98 ± 43	97 ± 38	75.6 ± 38	122 ± 42	0.09
Liver disease	1 (5)	0 (0)	0 (0)	1 (13)	0.44
History of cancer	5 (23)	2 (33)	1 (13)	2 (25)	0.68
NYHA functional class					
I—II	2 (9)	1 (17)	1 (13)	0 (0)	0.55
III	11 (50)	4 (67)	4 (50)	3 (38)	0.6
IV	9 (41)	1 (17)	3 (38)	5 (63)	0.24
LVEF (%)	56 ± 12	60 ± 9	52 ± 15	56 ± 9	0.48
STS score (%)	10.6 ± 5.8	10 ± 5.7	7.9 ± 5.2	13.5 ± 5.8	0.15
MR severity					
III	1 (4)	0 (0)	1 (13)	0 (0)	0.44
IV	21 (96)	6 (100)	7 (88)	8 (100)	0.44
MR mechanism					
P1 prolapse	3 (14)	2 (33)	0 (0)	1 (13)	0.03
P2 prolapse	11 (50)	3 (50)	4 (50)	4 (50)	0.22
A2 prolapse	3 (14)	1 (17)	1 (13)	1 (13)	0.13
Bivalvular prolapse	1 (4)	0 (0)	1 (13)	0 (0)	0.44
Secondary MR	4 (18)	0 (0)	2 (25)	2 (25)	0.44

Data are expressed as number (%) or mean ± standard deviation. BMI: body mass index; GHM: Groupe Homogène de Malades (diagnosis-related group); LVEF: left ventricular ejection fraction; MR: myocardial regurgitation; NYHA: New York Heart Association; STS: Society of Thoracic Surgeons'.

[a] There was no patient in severity level 4.

no significant difference between severity-level subgroups regarding demographic data and clinical status (Table 1).

Procedure outcomes and length of stay

Procedural and hospital follow-up data are presented in Table 2. The implantation of the MitraClip device was successful in all 22 patients, with one clip (55%), two clips (41%) or three clips (4%). The MR grade by transoesophageal echocardiography at the end of procedure was 1.1 ± 0.4, and 1.6 ± 0.8 by transthoracic echocardiography at hospital discharge.

The mean procedural time was 91 ± 30 minutes, and the length of hospitalization was 10 ± 9 days, with a mean cardiac ICU stay of 4 ± 7 days. For patients in severity level 3, the length of hospital stay was significantly longer than for other patients ($P < 0.001$), which was caused by a longer ICU stay.

Primary endpoint

The mean cost per patient for the Fig. 1 procedure was €30,039 ± 2476, and the mean revenue per patient was €30,331 ± 2720 Fig. 1. The difference between cost and revenue resulted in a profit of €292 ± 2039 per patient, and an overall profit estimated at €6429 for the institution.

Secondary economic endpoint: Profit according to severity level and device cost

The profit associated with the MitraClip® procedure by severity-level subgroup is presented in Table 3. A profit was made for patients in severity levels 2 and 3 (€807 ± 1399 and €938 ± 2662, respectively), but a loss was observed for patients in level 1 (€1255 ± 920).

When only considering patients benefiting from the lower device price (€21,000) after 2018 ($n = 5$), the profit

Table 2 Procedural and hospital follow-up data.

	All patients	GHM severity level[a]			*P*
	(*n* = 22)	Level 1 (*n* = 6)	Level 2 (*n* = 8)	Level 3 (*n* = 8)	
TOE MR grade at procedure end	1.1 ± 0.4	1.1 ± 0.5	1.1 ± 0.4	1.1 ± 0.2	0.98
TTE MR grade at discharge	1.6 ± 0.8	1.2 ± 0.8	1.6 ± 0.5	1.9 ± 1	0.26
Procedural time (minutes)	91 ± 30	89 ± 24	108 ± 26	76 ± 33	0.10
Hospital length of stay (days)	10 ± 9	6 ± 0	6 ± 1	16 ± 4[b]	0.02
ICU (days)	0 ± 1	0	0	1 ± 1	0.44
Cardiac ICU stay (days)	4 ± 7	2 ± 1	2 ± 0[c]	8 ± 3	0.09
Conventional unit stay (days)	5 ± 4	4 ± 1	4 ± 1	7 ± 2	0.2
Number of clips					
One clip	12 (55)	3	2[c]	7	0.04
Two clips	9 (41)	3	5[c]	1	0.04
Three clips	1 (4)	0	1	0	0.43

Data are expressed as mean ± standard deviation or number (%). GHM: Groupe Homogène de Malades (diagnosis-related group); ICU: intensive care unit; MR: mitral regurgitation; TOE: transoesophageal echocardiography; TTE: transthoracic echocardiography.
[a] There was no patient in severity level 4.
[b] $P < 0.001$ versus level 1 and level 2.
[c] $P < 0.05$ versus level 3.

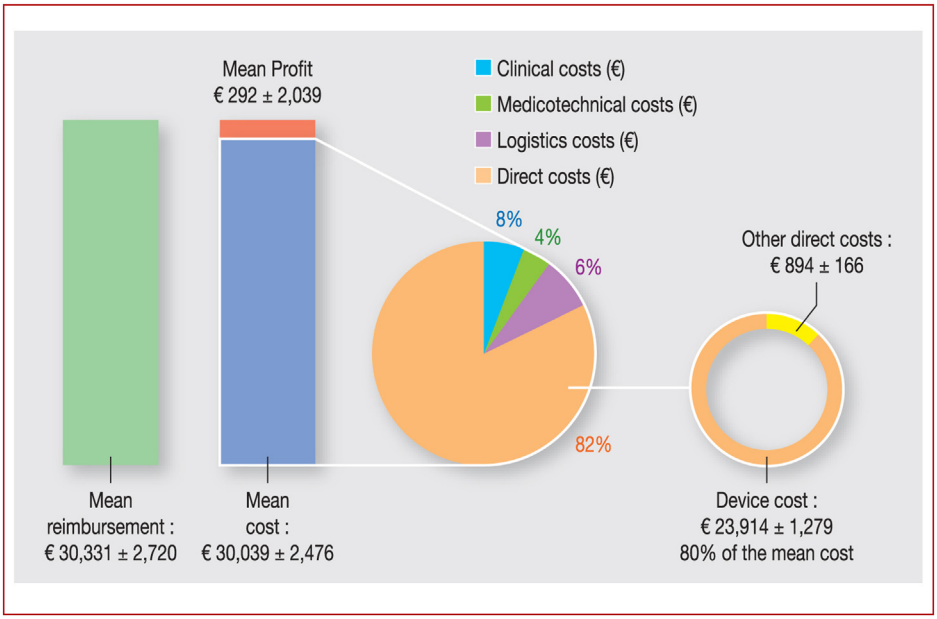

Figure 1. Costs associated with the MitraClip® procedure.

Table 3 Primary endpoint (per patient) by severity-level subgroup.

	All patients	GHM severity level[a]			*P*
	(*n* = 22)	Level 1 (*n* = 6)	Level 2 (*n* = 8)	Level 3 (*n* = 8)	
Total costs (€)	30,039 ± 2476	28,838 ± 1258	28,650 ± 1705	32,329 ± 2217[b]	< 0.01
Reimbursement (€)	30,331 ± 2720	27,583 ± 477[c]	29,457 ± 562	33,267 ± 2127[b]	< 0.01
Profit (€)	292 ± 2039	−1255 ± 920[c]	807 ± 1399	938 ± 2662	0.09

Data are expressed as mean ± standard deviation. GHM: Groupe Homogène de Malades (diagnosis-related group).
[a] There was no patient in severity level 4.
[b] $P < 0.001$ versus level 1 and level 2.
[c] $P < 0.001$ versus level 2 and level 3.

Table 4 Breakdown of costs per patient and by severity-level subgroup.

	Cost per patient	GHM severity level[a]			*P*
	(*n* = 22)	Level 1 (*n* = 6)	Level 2 (*n* = 8)	Level 3 (*n* = 8)	
Clinical costs (€)	2397 ± 1473	1773 ± 399	1715 ± 295	3547 ± 1982[b]	0.01
Medicotechnical costs (€)	1134 ± 170	958 ± 0[c]	1053 ± 0	1348 ± 0[b]	< 0.01
Logistical costs (€)	1699 ± 1046	1331 ± 267[c]	1169 ± 296	2506 ± 1401[b]	0.01
Direct costs (€)	24,808 ± 1279	24,776 ± 1196	24,713 ± 1422	24,928 ± 1355	0.95
Total costs (€)	30,039 ± 2476	28,838 ± 1258	28,650 ± 1705	32,329 ± 2217[b]	< 0.01
Device cost (%)	80	86	86	77	

Data are expressed as mean ± standard deviation. GHM: Groupe Homogène de Malades (diagnosis-related group).
[a] There was no patient in severity level 4.
[b] $P < 0.001$ versus level 1 and level 2.
[c] $P < 0.001$ versus level 2 and level 3.

was higher compared with the previous period, when the device was more expensive (€24,054), despite a decrease in reimbursement from the National Health Service. For these patients, profit increased to €1136 ± 2415, with four patients out of five having a positive balance.

Secondary economic endpoint: Breakdown of costs

The majority of costs (82%) were direct costs, mostly driven by the price of the device, representing 80% of the total cost and 96% of direct costs Fig. 1. Logistical costs represented 6% of the total cost, clinical costs 8% and medicotechnical costs 4%.

The breakdown of costs by severity-level subgroup is presented in Table 4. All costs were significantly higher for patients in severity level 3 ($P < 0.001$), except for direct costs, which did not differ between severity-level subgroups ($P = 0.95$). Clinical costs ($P = 0.76$) and logistical costs ($P = 0.31$) were not significantly different for patients in severity levels 1 and 2. Medicotechnical costs increased with severity level ($P < 0.01$).

Secondary clinical endpoints: Adverse events

There were no vascular or intraprocedural complications. Two patients needed a diuretic treatment for benign heart failure. One patient had increased MR at the end of hospitalization, despite a successful procedure; it was decided to continue with medical therapy because of the presence of co-morbidities and old age.

Discussion

To our knowledge, this is the first cost-revenue analysis performed for the MitraClip® procedure in a high-volume hospital. This small study, which included the ''real-life'' patients seen in clinical practice, suggests that the MitraClip® procedure is unprofitable, except for patients in Groupe homogène de malades (GHM) severity level 2 or 3.

The safety and efficacy of percutaneous mitral valve leaflet repair with a MitraClip® device has been demonstrated for primary MR in the randomized EVEREST II study [9], and for secondary MR associated with heart failure, in carefully selected patients [16], in two recent randomized trials: the Multicentre Study of Percutaneous Mitral Valve Repair MitraClip® Device in Patients With Severe Secondary Mitral Regurgitation (MITRA-FR) and the Cardiovascular Outcomes Assessment of the MitraClip® Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) [17,18].

Our study in primary MR (82%) and secondary MR (18%) treated with MitraClip® device implantation reported favourable clinical outcomes, with procedural success, duration and complications similar to those reported in other studies [19—21]. However, technological innovation is developing at a faster pace than economic growth. This represents a challenge for decision-makers who struggle between scarcity of resources and access to expensive innovations. As a consequence, pressure on hospitals is increased, and a significant proportion of French university hospitals are indebted. In 2016, about 200 MitraClip® procedures were performed in 30 centres allowed to implant the device in France [22]. To estimate the profit that hospitals can derive from specific procedures, such as the MitraClip® implantation, cost-revenue analysis is a valuable approach that is expected to provide support for resource allocation.

Our study was conducted in ''real-life'' conditions. The patient population mostly included the elderly with co-morbidities, and it was representative of the patients entitled to reimbursement of the MitraClip® procedure by the French National Health Service. Only two patients who received a MitraClip® device during the study period were excluded because of co-morbidities or complications outside the GHM code, which were incompatible with the methodology of the study. Despite a high Society of Thoracic Surgeons' score (10.6 ± 5.8%), and significant co-morbidities and dysfunctions, the patient population had an intermediate severity level, with no patient in severity level 4 and 73% patients in severity level 2 or 3. This confirms that the GHM severity classification used for pricing is independent of valve pathology, but is determined by co-morbidities and hospital complications.

The global costs of the MitraClip® procedure per patient in our institution were similar to those in other

French centres, based on the mean hospitalization costs (€29,808 ± 262) reported in the 2016 French National Scale of Health Costs (available online at http://www.scansante.fr/applications/enc-mco). The costs were lower than those observed in the USA ($54,896), despite a similar length of hospital stay (about 9 days) [20].

In our study, profit was only observed for patients in severity level 2 or 3. Among the six patients in severity level 1, only one presented a positive cost-revenue balance. The procedural global cost was driven by the price of the MitraClip® device. The impact of the device cost was higher in patients presenting a severity level 1 or 2, for whom it accounted for 86% of the total costs. To alleviate the economic burden of the MitraClip® procedure, a decrease in the price of the device will be necessary. Indeed, the lower device prices applied since 2018 have resulted in increased profit—a trend that is expected to last over the coming years.

Study limitations

This study was monocentric, but this limitation was balanced by high volume, use of standard patient recruitment and the fact that all French hospitals received the same reimbursement amount. The number of included patients, although high for a single institution performing MitraClip® implantation, remained too small to draw definite conclusions, but it was coherent, because the MitraClip® device concerned selected patients in France. Finally, the hospital costs and revenues were calculated after medical evaluation of the patients' severity level, and were dependent on the accuracy of the medical coding. Regardless of these limitations, the MitraClip® procedure was found to be profitable for the hospital in patients with GHM severity level 2 or 3.

Conclusions

This study shows that the percutaneous implantation of a MitraClip® device is a financially neutral procedure in an academic high-volume hospital. Profit is present only for patients in GHM severity level 2 or 3, and it increased for those patients who benefited from the lower device cost after 2018. The procedural cost was driven by the price of the MitraClip® device, and a significant reduction in the economic burden of this procedure will only be reached with a substantial decrease in the price of the device. This will be appreciated over the coming years.

Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

Disclosure of interest

The authors declare that they have no competing interest.

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