REVIEW ARTICLE

Efficacy and Safety of PARACHUTE® Device: systematic review

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SUMMARY

INTRODUCTION: *Heart failure due to an acute myocardial infarction is a very frequent event, with a tendency to increase according to improvements in the treatment of acute conditions which have led to larger numbers of infarction survivors.*

OBJECTIVE: *The aim of this study is to synthesize the evidence, through a systematic review, on efficacy and safety of the device in patients with this basic condition.*

METHODS: *Studies published between January 2002 and October 2016 were analysed, having as reference databases Embase, Medline, Cochrane Library, Lilacs, Web of Science and Scopus. The selection of studies, data extraction and methodological quality assessment of studies were examined by two independent reviewers, with disagreements resolved by consensus.*

RESULTS: *Only prospective studies without control group were identified. Six studies were included, with averages of 34 participants and follow-up of 13 months. Clinical, functional, hemodynamic and quality of life outcomes were evaluated. The highest mortality rate was 8.4% with 12-month follow-up for unspecified cardiovascular reasons, and heart failure rehospitalization was 29.4% with 36-month follow-up. Statistically significant improvements were found only in some of the studies which evaluating changes in left ventricular volume indices, the distance measured by the six-minute walk test, New York Heart Association functional classification, and quality of life, in pre and post-procedure analysis.*

CONCLUSIONS: *The present review indicates that no available quality evidence can assert efficacy and safety of PARACHUTE® in the treatment of heart failure after apical or anterior wall myocardial infarction.*

KEYWORDS: *Heart failure. Myocardial infarction. Equipment and supplies. Technology assessment, biomedical. Review literature as topic.*

INTRODUCTION

About 40% of cases of acute myocardial infarction (AMI) cases are associated with left ventricular (LV) systolic dysfunction, with the frequency of signs and symptoms of heart failure (HF) after AMI being around 25%. Data indicate that the latter condition is quite frequent and will tend to increase as improvements in the treatment of acute conditions have led to larger numbers of AMI survivors[1].

In 2007, a percutaneously implanted structural cardiac device called PARACHUTE® (PercutAneous Ventricular RestorAtion in Chronic Heart FailUre due to Ischemic HearT DiseasE) was patented (Figure 1). Manufactured by Cardiokinetix, Menlo Park, CA, it was developed for patients with post-AMI HF[2] in order to segregate the dysfunctional LV region, minimizing systolic and diastolic volumes, and con-

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sequently limiting stress on the myocardium and improving hemodynamic as well as its functional capacity[3].

Preliminary studies conducted in Europe and the United States have been driving the performance clinical trials to define the long-term efficacy and safety of PARACHUTE®. Some of these studies have already published their results, emphasizing the relevance in the search and synthesis of the existing clinical results, to carry out the monitoring of the technological horizon and to advise the future decision processes pertinent to the ventricular partitioning device.

The present work was conceived considering that PARACHUTE® is a recent, high cost innovative therapy. In Brazil, experimental research has already begun and the device is being evaluated for sanitary registration in the national regulatory agency, which may lead to future demands for incorporation into the payment schedules of the Brazilian health system. The results of the technology in terms of efficacy and safety have not yet been established, no systematic review of these scopes has been identified and the prevalence of the underlying condition tends to increase due to population aging.

Thus, the objetive of this study was to summarize the evidence, through a systematic review, regarding the efficacy and safety of the ventricular partinioning device in patients with HF after apical or anterior wall AMI.

METHODS

The question of the present systematic review was: "Is the ventricular partitioning device (PARACHUTE®) safe and effective for the treatment of heart failure of ischemic aetiology after apical or anterior wall AMI when compared to the other available treatments?"

In order to answer this question, the following bibliographic databases were searched: Embase, Medline (via PubMed), Cochrane collaboration, Lilacs, Scopus and Web of Science, covering the period from January 2002 to April 2016. There were no restrictions of language in the bibliographic searches. The searches were updated monthly until the completion of the study (October 2016) in order to capture possible scientific productions that had been published later on.

FIGURE 1: PARACHUTE®

In addition, a cross-reference search was made in the articles found and in previously published narrative review articles on the topic. Annals of congresses in the area of Cardiology in the last five years, pages of the medical societies of the areas of Cardiology and Interventional Cardiology, and the databases of ClinicalTrials.gov, Cochrane Central Register of Controlled Trials (CENTRAL), World Health Organization and the Brazilian Registry of Clinical Trials were also consulted. Research by evaluations conducted by health technology assessment agencies belonging to the International Network of Agencies for Health Technology Assessment (INAHTA) was made complemented. Finally, we examined the EuroScan International Network, the study base of systematic reviews PROSPERO and the pages of Cardiokinetix, manufacturer of the device.

The search was restricted to humans and the strategy used descriptors, when available, and free words in the title, abstract and text of the manuscripts, related to the disease and the intervention. The complete search strategies used in each database can be made available upon request to the authors.

The selection of the studies was performed based on the initial analysis of the title and abstract, followed by evaluation of the full text by two independent evaluators, with resolution of the disagreements in both stages by consensus. Full-text studies published in languages other than English, Spanish and Portuguese were excluded but registered for the identification of possible language bias. The eligibility criteria used were substantiated by the acronym PICOS. Thus, they had to be randomized or non-randomized controlled clinical trials and observational studies (cohort, case control, and series of cases ≥ 10 patients enrolled) that evaluated the efficacy and safety of the intervention (PARACHUTE®) in the adult patient population (> 18 years old) with HF after apical or anterior wall AMI, in which the comparators, when available, were a ventricular assist device, conventional clinical treatment and surgical treatment; and that had any of the following outcome measures:

mortality from HF, AMI, stroke and non-specified cardiovascular causes, and from any cause; rehospitalization for HF; successful implantation of the device with regard to selected patients; maintenance of the implanted device by time (in months) of follow-up; changes in LV volume index; change in walking distance as measured by the 6-minute walk test; changes in quality of life as measured by the EuroQol five dimension questionnaire (EQ-5D) and Minnesota Living with Heart Failure (MLHFQ) instruments; improved functional classification of the New York Heart Association (NYHA); and frequency of adverse events/complications.

The methodological quality of the studies was also evaluated by the same pair of reviewers, with disagreements resolved by consensus, using the Quality Appraisal Checklist for Case Series Studies tool[4].

Data from the included studies were extracted in duplicate and independently by two reviewers in a standardized electronic collection form, prepared in the public domain EpiData® application. The form was previously tested on selected articles and adjustments were made for adequacy purposes, and it was subsequently reapplied to the entire set of articles.

The results of the studies were analysed using frequency measurements, presenting the continuous mean or median variables, followed by the respective standard deviations. Excel® version 2010 and Stata® version 13 were used to calculate and prepare presentation formats.

The study was approved by the Research Ethics Committee of a federal institute of assistance and education under number 48942915.1.0000.5272, and its protocol was registered on the systematic review base Prospero (CRD42016034179).

RESULTS

Studies selection

This systematic review totalled the inclusion of six studies[5-10] and the flowchart with the results of the selection phases is present in Figure 2.

Characteristics of the studies and participants included in the systematic review

All six studies included in the systematic review are uncontrolled follow-up, corresponding to series of cases with patients enrolled consecutively. The studies were published between 2010 and 2016, one of them developed in China[10] and the others in European centres, one of which was also developed in the United States[6]. Four studies were multicentric[5,6,9,10].

The number of participants effectively submitted to the implantation of the device ranged from 8 to 100 patients, with a mean of 34 patients, median of 23.5 and a standard deviation of 30.9. It should be noted that, in some articles, the number of enrolled participants was higher, but PARACHUTE® was not implanted in all patients recruited, most often as a result of unfavourable anatomy (inadequate ventricular apex dimensions and inappropriate architecture, geometry and trabeculation of the LV).

Functional rating of NYHA from II to IV, age> 18 years old, FEVE between 15% and 40%, and LV anteroapical wall motility disorder were inclusion criteria in 100% of the studies, as well as recent percutaneous coronary angioplasty or myocardial revascularization and valve disease were exclusion parameters in all studies.

The mean age of the patients in the studies ranged from 56.9 to 71.3 years. The vast majority of participants were male, in proportions ranging from 62.5% to 94.4%. The participants' weight and height were reported only in two articles[7,9] and the BMI also in two[9,10], with averages of 27.6 kg/m² (SD ± 3.9) and 25 kg / m² (SD ± 2.2).

Two studies did not present the patients' NYHA functional classification,[6,7] although there is a figure present in Costa et al.[7] which suggests that more than half belonged to class III.

High blood pressure and diabetes mellitus were risk factors for heart disease reported in all studies. Smoking also had high participation rates (from 40% to 80%) in most of the studies.

Previous cardiovascular procedures were described in all studies, mainly revascularization or coronary angioplasty.

Except for two studies, Sagic et al.[5] and Yang et al.[10], all others mentioned participation of patients with comorbidities. Two implants of the device associated with MitraClip as a consequence of severe or moderate/severe mitral valve regurgitation were reported in a manuscript[8].

Previous use of medication by participants was quite diverse. However, in 83% of the studies[5-7,9,10], all patients used antiplatelet or anticoagulant medication (acetylsalicylic acid or warfarin) after the procedure, with the use of diuretics, beta-blockers and ACE inhibitor, in variable proportions (data not included in the table).

TABLE 1 - GENERAL AND CLINICAL OUTCOMES ASSESSED IN THE SYSTEMATIC REVIEW

Author	Follow-up time (m)	% Loss of follow-up* (m)	% Implant Success	% Maintenance of the implanted device* (follow-up months)	% Re-admission due to HF* (follow-up months)	% Mortality due to (follow-up months)	Adverse events/ complications (% of patients)
Sagic et al.(5)	12	13.3 (3 m) 13.3 (6 m) 13.3 (12 m)	86.7	86.7 (3 m) 86.7 (6 m) 86.7 (12 m)	0	Infection 6,7 (3m)	DD (6.7), LC (61.5), VC (6.7)
Bozdag-Turan et al.(6)	3	0 (3 m)	100	100 (3 m)	0	0	0
Costa et al.(7)	36	8.8 (12 m) 20.5 (24 m) 32.3 (36 m)	91.2	91.2 (3 m) 82.3 (12 m) 79.4 (24 m) 67.6 (36 m)	11.8 (12 m) 26.5 (24 m) 29.4 (36 m)	CM - 6.5 (12 m), OC - 3.7 (12 m); cancer - 3.7 (36 m)	Infection (2.9), PE (11.8), VC (14.7), LVC (2.9), DC (2.9)
Schmidt et al.(8)	12†	6.2 (3 m) 12.5 (6 m) 25 (12 m)	93.8	93.8 (3 m) 87.5 (6 m) 75 (12 m)	NI	CVA - 6.7 (6 m), infection - 6.7 (12 m), OC - 6.7 (12 m)	DD (6.2), LC (20), arrhythmia (33.3)
Thomas et al.(9)	12	3 (3 m) 5.1 (6 m) 8.7 (12 m)	97	97 (3 m) 92 (6 m) 84 (12 m)	24.1 (12 m)	OC - 1.0 (6 m), CM - 8.4- (12 m)	DD (1), ECC (3), ET (3.3), PE (1), arrhythmia (1), VC (4), MI (1)
Yang et al.(10)	3	6.4 (3 m)	96.8	93.5 (3 m)	NI	OC (3,2-3 m)	CVA (3.2), VC (3.2), AVE (3.2)

Notes: † - Estimated follow-up time 12 months, three patients died after three months and five have not yet closed the total scheduled follow-up time; * - cumulative percentage. Source: Own preparation. **Key:** CVA - cerebrovascular accident; ECS - emergency cardiac surgery; DC - complication related to the nitidol frame of the device; VC - vascular complications; LVC - left ventricular calcification; DD - displacement of the device; PE - peripheral embolization; TE - thromboembolic events; MI - mitral valve injury; m - months; CM - non-specified cardiovascular mortality; OC - other causes; LC - leakage between the static and dynamic chamber of the left ventricle; NI - not informed. **Name of the review authors:** Roberta da Silva Teixeira, Bruna Medeiros Gonçalves de Veras, Kátia Marie Simões and Senna, Rosângela Caetano

TABLE 2 - FUNCTIONAL, HEMODYNAMIC AND QUALITY OF LIFE OUTCOMES IN THE STUDIED POPULATIONS

Author	Mean NYHA (SD)		Mean walking distance	Quality of life Mean MLHFQ score (SD)		% Mean EFLV (SD)		Mean LVESVi (SD)		Mean LVEDVi (SD)	
	Before	After (m)	Delta* (m)	Before	After (m)	Before	After (m)	Before	After (m)	Before	After (m)
Sagic et al.(5)	2.2 (±0.6)	6 m – 1.3 (±0.5)[1] 12 m – 1.2 (±0.4)[1]	6 m – 27 12 m - 43[2]	21.7 (±18.9)	6 m – 16.7 (±12.3) 12 m – 20.8 (±16.9)	28 (±7)	6 m - 32 (±7) 12 m - 33 (±9)[2]	189 (±45)	6 m -142 (±29)[1] 12 m - 151 (±48)[1]	260 (±47)	6 m - 208 (±33)[1] 12 m - 222 (±58)[3]
Bozdag-Turan et al.(6)	2.8 (±0,7)	3 m – 1.6 (±0.5)[2]	3 m - 190[2]	29 (±13)	3 m - 15 (±10)[2]	NI	NI	NI	NI	NI	NI
Costa et al.(7)	NI	NI	12 m – 16.1	38.6 (±5.1)	12 m – 28.4 (±4.4)[4]	27	6 m – 30 12 m – 29.5 24 m – 27.8 36 m – 23.0	93.9	6 m – 74,1[5]; 12 m – 77,0[5] 24 m – 81.6 36 m – 89.4	127.7	6 m – 105,8[5]; 12 m – 108,7[5] 24 m – 112.8 36 m – 115.5
Schmidt et al.(8)	NI	NI	NI	NI	NI	24.7 (±7.2)	NI	NI	NI	NI	NI
Thomas et al.(9)	2.6 (±0.5)	12 m – 2.0 (±0.7)[1]	12 m - 25[3]	NI	NI	29.2 (±7.9)	12 m - 31 (±7.6)	84 (±24)	12 m – 70.5 (±24)[5]	117.3 (±26,3)	12 m – 99.1 (±27.3)[5]
Yang et al.(10)	NI	NI	3 m – 7.8	NI	NI	30 (±5.4)	3 m – 35.8 (±6.8)[1]	77.5 (±20)	3 m – 53.1 (±17)[5]	110.8 (±26.1)	3 m – 82.1 (±21.3)[1]

Notes: 1 - p <0.001; 2 - p <0.05; 3- p <0.01; 4 - p <0.002; 5 - p <0.0001; * - difference between the average distance travelled per month of follow-up. Key: SD - standard deviation; EFLV - ejection fraction of the left ventricle; LVEDVi - left ventricular end-diastolic volume index; LVESVi - left ventricular end-systolic volume index; m - months of follow-up; MLHFQ - Minnesota Living with Heart Failure Questionnaire; NI - not informed; NYHA - New York Heart Association.

Outcomes assessed in the studies included

For the adequate evaluation of the reported outcomes, it is important to highlight that the follow-up time in the trials ranged from 3 to 36 months, with mean and median 13 and 12 months, respectively.

Analyses of general and clinical outcomes are set forth in Table 1. In turn, functional, hemodynamic, and quality of life outcomes are shown in Table 2.

Changes in quality of life measured by the ML-HFQ instrument were analysed by Sagic et al.[5], Bozdag-Turan et al.[6] and Costa et al.[7]. Yang et al.[10] analysed the improvement of this parameter using the EQ-5D instrument and visual analogue scale (VAS). The VAS value increased by 11.5 points, showing a statistically significant improvement ($p < 0.01$) with three months of follow-up.

Quality of evidence

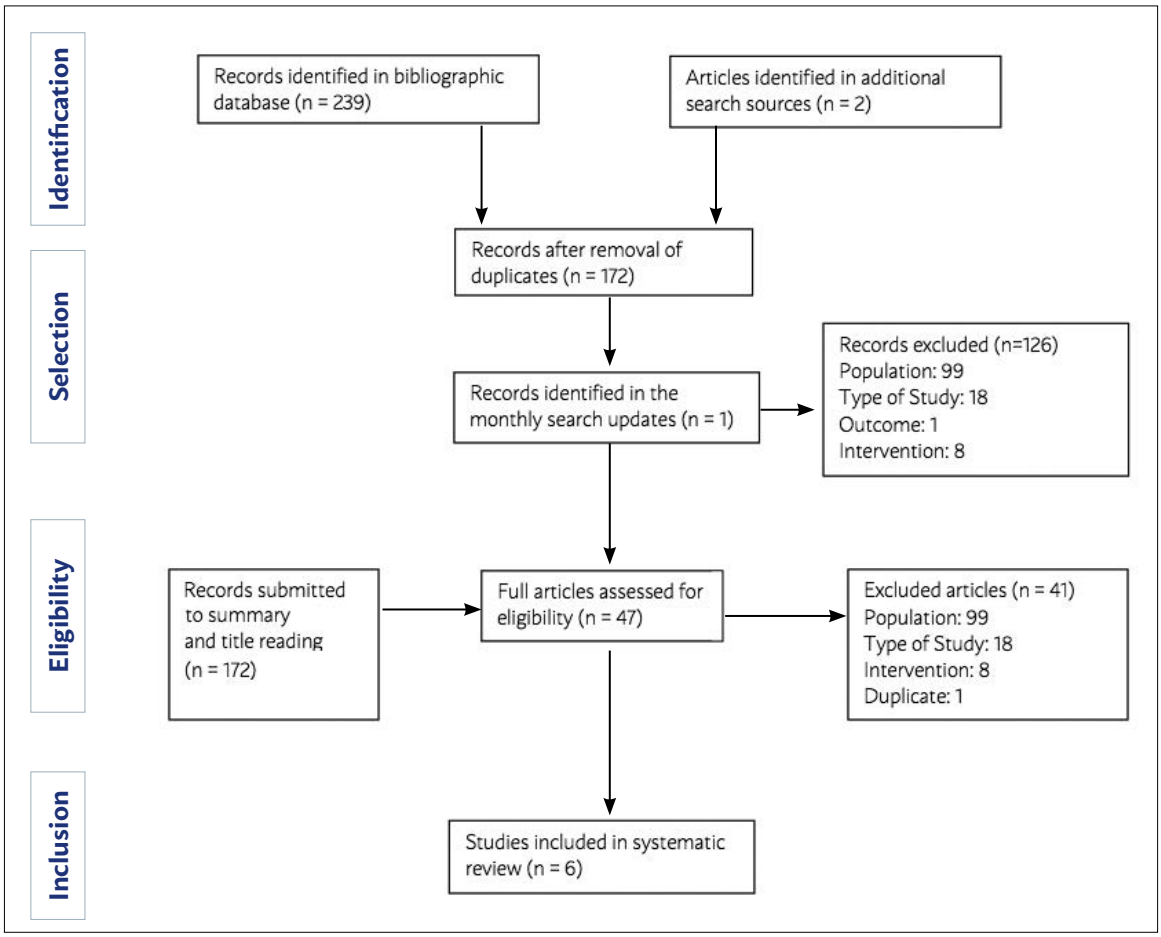
Of the 20 criteria evaluated by the Quality Appraisal Checklist for Case Series Studies tool[4], ten were fully met by all studies in this review.

Two other criteria - a detailed description of the characteristics of the patients included in the studies and the intervention of interest - reached 80% attendance rates. On the other hand, in the criteria "patients started their participation in the study at a similar point of the disease" and "outcome assessors were blinded about the intervention that the patients received", the attendance percentage was less than 40%, and in the criterion "the follow-up was long enough for important events and outcomes", percentage was 20%.

A partial description of co-interventions was performed by all studies, and the percentage of complete care was null for the criterion "the study provided an estimate of the random variability in the analysis of relevant outcome data."

The Costa et al.[7] study was the one with the highest proportion of criteria: 16 out of 20 (80%). The work of Sagic et al.[5], Thomas et al.[9] and Yang et al.[10] also achieved a very good percentage (meeting 15 criteria), with that of Bozdag-Turan et al.[6] presenting the worst individual methodological quality (meeting 60% of the criteria).

FIGURE 2: FLOWCHART OF THE SELECTION OF SYSTEMATIC REVIEW STUDIES



DISCUSSION

This systematic review was based only on uncontrolled follow-up studies, due to the absence of randomized controlled trials (RCTs) published until October 2016.

The quality of evidence available on the efficacy and safety of the device is still rather precarious. Although the case series included present a reasonable quality standard, the findings are derived from a study design that, in essence, does not adopt procedures that allow the control of biases that can influence the results obtained.

A randomized controlled trial - PARACHUTE IV[11] - is currently underway in the United States. This study provides the perspective of supplementing the evidence about the device and establishing its effective utility in the treatment of patients with heart failure of ischemic aetiology.

Observational studies may be a favourable complement in the systematic analysis of adverse events, especially when controlled clinical trials evaluating the efficacy of a technology are scarce[12,13]. In certain situations, even in the absence of RCTs, such studies can provide important information to decision makers, resulting in a complementary source of evidence of low cost, rapid and valuable substitute for technologies in which the diffusion process has already begun[14]. In this scenario, cohort and case-control studies are an alternative to obtain an estimate of the effects of a specific treatment, although the level of evidence from the observational studies is mostly less strong than the RCTs because of the difficulty to control some biases[15].

Case series, due to absence of control group, are prone to biases related to selection, performance, friction and reporting, and to confusion. It is not possible to affirm that its results are attributable to the intervention and do not generate direct statistical comparisons, making it impossible to obtain more robust and unbiased evidence about treatment efficacy[16]. However, this type of study, although less conclusive in terms of evidence, may be the only source of information available to inform health decisions about the implementation of emerging technologies[17,18], as is the case of the device investigated herein. Thus, in the absence of other methodologically more robust types of study, there may be strong assumptions for inclusion of case series in a systematic review or evaluation of a technology in the early stages of development[19].

In this review, the number of papers published is small and, with the limitations set forth, the number of participants in the studies is also very restricted, since only two studies included more than 30 participants. These aspects are further strained by the small follow-up times and the size of the follow-up losses, weakening the analyses of the most relevant clinical outcomes, such as the mortality of patients who underwent device implantation and HF readmissions, as well as the few differences in hemodynamic, functional and quality of life outcomes, assessed before and after the intervention.

It is noteworthy that in the distance-relevant outcome measured by the 6-minute walk test, even considering the 30-meter delta minimum as a reference as the clinically significant minimum difference in the distance travelled,[20] it is observed that in only two studies was evidenced relevance in this regard.

PARACHUTE® has some benefits compared to the other mechanical technologies currently used to treat the clinical situation on the screen. When implanted percutaneously, it prevents the morbidity and mortality of open surgical intervention[21]; it has no external component to the heart, preserving the pericardium and the pericardial space; it can be readily used in patients who do not require myocardial revascularization surgery or other concomitant procedures; and does not prevent the use of other devices adopted in the area of cardiology, such as cardiac resynchronization therapy devices or devices for mitral valve regurgitation[22].

On the other hand, PARACHUTE® is limited in aspects such as the lack of systolic assistance, increased systolic volume and cardiac output, intervening in its ability to act in patients with advanced heart failure[23].

The case report of Ravi et al.[24], in which a patient had deterioration of the functional and hemodynamic outcomes after 24 months of PARACHUTE® implantation, which led to their removal and the implantation of the ventricular assist device, has led to a debate about the efficacy time of PARACHUTE®.

In addition, the findings in the study by Costa et al.[7], included in this systematic review, in which the improvement in LV volumes and LV ejection fraction indexes attained at 12 months of follow-up were not sustained after 36 months of implantation of the device may suggest that this hemodynamic worsening is not by chance, but rather because the device appears to have a relatively short duration of efficacy. Thus, it is possible that the technology could be used

as a link until the implantation of a ventricular assist device or heart transplant[25], instead of working as a definitive intervention in the treatment of patients with heart failure of ischemic aetiology.

After AMI, the prognosis is dependent on left ventricular function[26]. Thus, the exact identification of reversible ventricular dysfunction is essential in the evaluation of patients' treatment[27,28].

The time between AMI and the device implantation procedure needs to be evaluated in the selection of patients. However, it was observed that, among the studies included in the review, only two[5,6] clearly defined this criterion, and two others[7,9] indirectly considered the criterion when establishing that the applicant patients had to be in appropriate clinical treatment of HF in the three months which preceded their selection in the studies.

Thromboembolic events are one of the most important concerns with PARACHUTE®. The percentage of this complication (3.3% of the participants) was described only in one study[9], suggesting that the other studies included in the review reached the goal of reducing these potential events with the use of antithrombotic drugs after device implantation. These findings appear encouraging when compared to thromboembolism rates related to their direct "competitor", the ventricular assist device, whose complication rates are around 20%[29-31]. However, they need to be cautiously interpreted, since their primary studies were not controlled trials and most follow-up times were not very extensive.

The study by Yang et al.[10] showed a better result of systolic function, specifically LV ejection fraction and LV end-systolic volume index, compared to the other studies included in the review. This hemodynamic improvement can be explained by the fact that most patients (93.6%) were treated at the beginning of the progression of HF (NYHA class II). Thus, discussions about the ideal time to implement PARACHUTE® are equally relevant to enhance its benefits to the underlying condition.

Some limitations of this systematic review need to be mentioned. The review identified only observational studies, with a very restricted number of participants and, for the most part, short-term follow-up time. In addition, the measures of outcomes evaluated before and after the implantation of the device did not always reach expressive degrees and, due to the study designs, with absence of control group and blinding, it is not possible to disregard the presence of a potential bias in the adjudication process. The placebo effect in the studies also cannot be disqualified, especially with the use in surrogate and functional outcome studies. Outcomes such as NYHA's functional class, which involve a certain degree of subjectivity in its measurement, may have been misdiagnosed because of the absence of blinding.

CONCLUSIONS

Although PARACHUTE® is an innovative technology, considering the quality of the evidence presented and the results of the measures of outcomes evaluated, it is concluded that there is no available quality evidence that can assert the efficacy and safety of the technology in the treatment of patients with heart failure after acute myocardial infarction or anterior myocardial wall infarction.

The efficacy and safety of PARACHUTE® still need to be evaluated in the future through controlled studies with long-term follow-up and larger sample sizes.

RESUMO

INTRODUÇÃO: *Insuficiência cardíaca após infarto agudo do miocárdio é um evento bastante frequente, que tende a aumentar conforme as melhorias que o tratamento dos quadros agudos têm acarretado a números maiores de sobreviventes de infarto.*

OBJETIVO: *A revisão sistemática sumarizou as evidências relativas à eficácia e segurança do dispositivo de partição ventricular (PARACHUTE®) em pacientes com IC pós-IAM apical ou de parede anterior.*

MÉTODOS: *Foram analisados estudos publicados entre janeiro de 2002 e outubro de 2016 nas bases Embase, Medline, Colaboração Cochrane, Lilacs, Web of Science e Scopus. A seleção dos estudos, a extração dos dados e a avaliação de qualidade metodológica foram realizadas por dois revisores independentes, com as discordâncias resolvidas por consenso.*

RESULTADOS: *Somente estudos prospectivos sem grupo controle foram identificados. Seis estudos foram incluídos, com média de 34 participantes e de follow-up de 13 meses. Foram avaliados desfechos clínicos, funcionais, hemodinâmicos e qualidade de vida. O maior percentual de re-hospitalização por IC foi de 29,4%, com 36 meses de seguimento, e de mortalidade foi de 8,4%, com 12 meses de seguimento, por motivos cardiovasculares não especificados. Melhorias estatisticamente significantes foram constatadas em alguns dos estudos que avaliaram mudanças nos índices de volume do ventrículo esquerdo, distância medida pelo teste de caminhada de 6 minutos, classificação funcional da New York Heart Association e qualidade de vida, em análises do tipo antes e depois do procedimento.*

CONCLUSÕES: *A presente revisão indica que não existem evidências de qualidade disponíveis que permitam afirmar a eficácia e segurança do PARACHUTE® no tratamento da condição de base.*

PALAVRAS-CHAVE: *Insuficiência cardíaca. Infarto do miocárdio. Equipamentos e provisões. Avaliação da tecnologia biomédica. Literatura de revisão como assunto.*

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