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Review paper

Transapical Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve using the V-Clamp system – A promising approach for minimally invasive cardiology in veterinary and experimental human medicine

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Abstract

Mitral valve (MV) regurgitation (MVR) is mainly associated with mitral valve leaflet prolapse. The leading cause of MV leaflet prolapse is degeneration of the mitral valve leaflets or functional MVR. Until recently, there has been a scarcity of surgical options for minimally invasive mitral valve repair in dogs. In contrast, humans often have forms of MVR that do not qualify for conventional heart surgery or existing minimally invasive mitral valve repair methods. Transapical Transcatheter Edge-to-Edge Repair (TEER) of the MV is an innovative new method that uses special clips that are inserted into the heart through apical punctures. This technique enables effective closure of the defective valve without necessitating a traditional thoracotomy or opening the heart. It is the first minimally invasive method for valve clamping in dogs and a new option available for humans suffering from severe MVR.

In this article, we summarize the knowledge of TEER and its use in humans and dogs.

Keywords: mitral valve repair, mitralip, V-Clamp, dog

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Introduction

Mitral regurgitation (MR) is a serious condition that affects both humans and animals, especially dogs. Mitral valve regurgitation (MVR) is associated with several factors, including leaflet inflammation, dilation of the annulus, and prolapse of the mitral valve (MV) leaflets (Del Forno et al. 2020). The primary cause of MV leaflet prolapses is the degeneration of the mitral valve leaflets, which includes localization of degenerative changes primarily concentrated in the anterior leaflet (A) in dogs or in the posterior leaflet (P) in humans (Roberts et al. 1987, Terzo et al. 2009). In humans, functional MVR can occur due to leaflet tethering, which results from post-ischemic displacement of the papillary muscles, as well as from abnormal left ventricular (LV) function – specifically, motion abnormalities associated with asymmetric leaflet restriction or annular dilation. These issues can also arise in dogs, especially during the progression of dilated cardiomyopathy (DCM) (Fig. 1). The long-term presence of MVR leads to remodeling of the left atrium (LA) and LV (Huang et al. 2023).

The most severe degrees of MVR in humans, namely moderate-to-severe and severe, are indications for mitral valve treatment. Several strategies for mitral valve treatment are currently available. The decision on which treatment method to choose is based on an assessment of the benefits and risks for patients (Majmundar et al. 2024). Low-risk patients who can survive open-heart surgery often have better long-term results after traditional valve repair or replacement. Conversely, high-risk patients, particularly those who are older or have multiple comorbidities, may benefit more from minimally invasive techniques, which carry lower risks of complications (Nishimura et al. 2017). Among these methods are clamping of the mitral valve leaflets from the atrial (MitraClip) or transcatheter mitral valve replacement and chordal implantation (Borgarelli et al. 2017).

In dogs, there have been limited surgical options for low-invasive mitral valve repair until recently. To date, myxomatous mitral valve degeneration (MMVD), the leading cause of MVR in dogs, can be surgically addressed through a procedure known as annuloplasty with trans-atrium access (Aoki et al. 2022). This complex operation involves opening the heart and requires cardiopulmonary bypass. The cost of such a procedure is well beyond the means of most dog owners who would be eligible for mitral valve repair. In turn, the MitraClip used in humans is not adapted to the size of both the heart and the femoral veins in dogs. In humans, the MitraClip system is inserted through the femoral vein, providing percutaneous access to the right atrium. An atrial septal puncture needle creates a lumen for the catheter and the clip tucked inside, with the arms classically positioned toward the manipulator (Kataoka et al. 2023). The complex procedure of delivering the MitraClip and the complicated method of placing the clip conveniently on the valve can cause severe technical problems. Furthermore, certain forms of MVR involving a gap wider than 15mm can be particularly difficult to repair using the MitraClip (Schnitzler et al. 2021).

In response to these issues, the development of minimally invasive techniques, such as transapical mitral valve repair, is becoming increasingly important (Pan et al. 2019a) (Table 1). One innovative method, known as Transapical Transcatheter Edge-to-Edge Repair of the Mitral Valve (abbreviated as V-Clamp), utilizes special clips that are inserted into the heart through apical punctures. This approach allows for the effective closure of a failing valve without the need for a traditional thoracotomy, which involves opening the heart (Ge et al. 2020). However, this method carries a higher risk of tissue damage compared to the MitraClip technique due to the need for direct puncture of the left ventricular wall, which limits its use to a select group of patients. Therefore, the V-clamp could become an additional therapeutic option, the use of which is expected to increase over time. Moreover, in the case of dogs, there has been an opportunity to introduce a device of the same type into veterinary medicine (Sasaki et al. 2022). Thus, creating a new branch of veterinary cardiology that includes minimally invasive methods for mitral valve repair.

The article presented here aims to summarize the currently existing knowledge of the V-Clamp based on clinical studies in dogs and humans, as well as preclinical studies in animal models.

Introduction of a new transcatheter device for mitral valve repair

Surgery procedure

The procedure is performed under general anesthesia under TEE guidance. Interestingly, while fluoroscopy is used in veterinary medicine, it is not necessary in human medicine (Li et al. 2023). After an anterolateral mini-thoracotomy, the heart apex must be located precisely using a four-chamber projection. A cotton bud identifies the apex by myocardial thinning. After this, a double support suture stabilizes the area. A transapical puncture allows insertion of the valve-crossing device. The catheter tip is placed into the LA (about 11–12 cm in humans), followed by the valve-grasping device.

In 3D MV imaging and 2D X-plane projection,

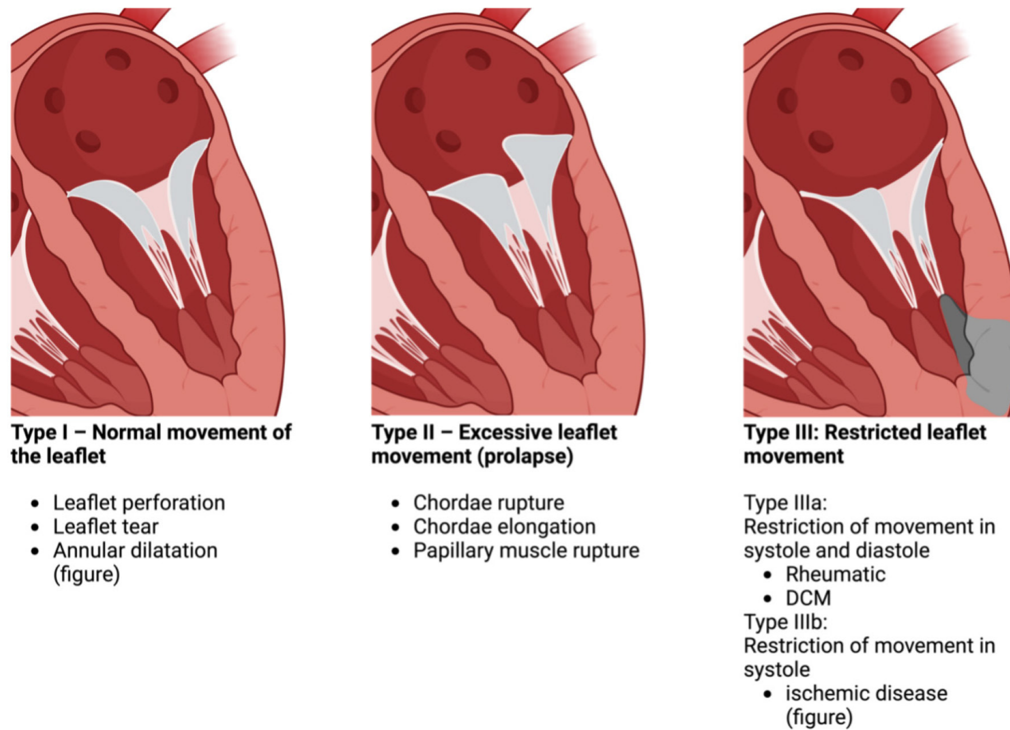

Fig. 1. Mitral regurgitation is categorized according to the valve leaflet movement (Carpentier).

Table 1. A summary of ongoing preclinical and clinical studies on the utility of V-Clamp in dogs.

Type of study	Model	Funding source	Country	Study group	Source
Preclinical	Porcine	Institutional research grant from Medtronic and Abbott Vascular	China	13	(Pan et al. 2019a)
Preclinical	Porcine	Grant Nos. 19441915800 & 18ZR1436100	China	40	(Ge et al. 2020)
Preclinical	Dog	Grant No. ID:R02-12	China	2	(Sasaki et al. 2022)
Clinical	Dog	Support from Hongyu Medical Technology	China	8	(Liu et al. 2020)
Clinical	Dog	Support from Hongyu Medical Technology	USA	48	(Potter et al. 2024)
Clinical	Dog	Grant Nos. FOOD66310017 and HEAF673100100	Thailand	1	(Kijtawornrat et al. 2024)
Clinical	Dog	-	Thailand	4	(Petchdee et al. 2024)
Clinical	Human	Grant No. Clamp-1 NCT03869164	China	12	(Pan et al. 2019b)
Clinical	Human	Grant No. 19441915800	China	35	(Ge et al. 2021b)
Clinical	Human	Grant No. 2020YFC2008100	China	12	(Li et al. 2023)
Clinical	Human	Grant at Zhongshan Hospital of Fudan University, Beijing Fuwai Hospital, and West China Hospital of Sichuan University	China	12	(Long et al. 2022)
Clinical	Human	Grant Nos. CLAMP-2 NCT03869164 and YW2021-002	China	102	(Pan et al. 2023)

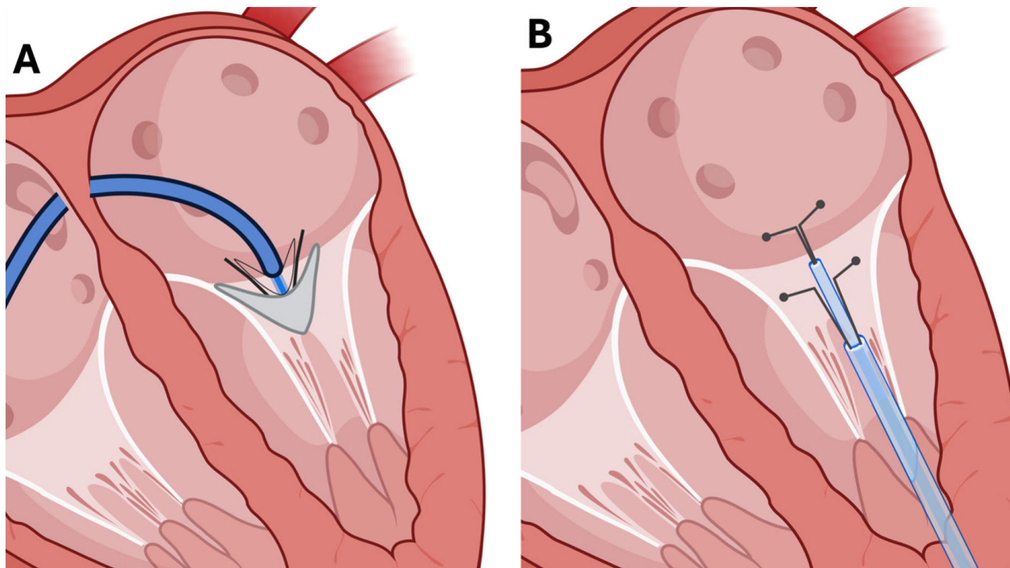

Fig. 2. Diagram showing the difference between MitraClip (A) and V-Clamp (B). The MitraClip offers percutaneous access, via the femoral vein. Then, by puncturing the interatrial septum in the *fossa ovalis*, the clip is 'lowered' to the level of the MV. The V-Clamp, on the other hand is inserted through an anterolateral mini-thoracotomy and reaches the MV level via a transapical puncture.

the clip must be centered in the regurgitant jet and perpendicular to the MV commissure. From the LA, it is withdrawn so that the rear arms clamp the ventricular surface and the front arms the atrial surface (Fig. 2). Clamping is achieved by bringing the arms together, and MV function is assessed by four parameters: leaflet insertion, residual regurgitation, geometry, and stenosis (Ge et al. 2021a). The difference in leaflet length pre- and post-clamping indicates insertion length (optimal 5 mm in humans, 4–5 mm in dogs). Residual regurgitation or multiple jets may require another clip. MV geometry after clamping is symmetrical and two-hole, but annulus narrowing may cause stenosis; the pressure gradient must not exceed 5 mmHg (Neuss et al. 2017). After procedures, patients are discharged after 24-48 hours and receive antiplatelet therapy for 3 months (clopidogrel in dogs; clopidogrel and aspirin in humans) (Pan et al. 2019b, Long et al. 2022, Potter et al. 2024).

Preclinical study

In preclinical work, the first utility of a V-Clamp was tested on thirteen healthy young adult swine (Yorkshire pigs) (Pan et al. 2019a). All subjects lived without complications until the last day of the experiment, except for one pig, which died of pneumonia on day 2. In the subjects that underwent the implantation procedure, a two-orifice MV was obtained with a highly fixed clip. However, the report included information about the subsequent detachment of the two devices from the posterior leaflet (Pan et al. 2019a). Subsequently, healthy Beagle dogs were used to assess the feasibility of the procedure (Sasaki et al. 2022). After the procedure, one individual showed features of pulmonary edema, which was not accompanied by other symptoms such as exercise intolerance. In another porcine model, MR3+ was induced using chordae tendineae undercutting. In all of them, the V-Clamp reduced MVR to ≤ 2+, and in almost 30% of cases, residual MVR was not present (Ge et al. 2020). Furthermore, clamping, which limits the effective area of the hole, did not induce a gradient above 5mmHg in any of the pigs (Ge et al. 2020).

Use of the V-Clamp

Clinical study – Human medicine

By design, the V-Clamp can cause more severe damage to cardiac tissue than the MitraClip because it pierces the apex, i.e., the thicker segment of the cardiac muscle. In contrast, the MitraClip pierces the very thin, partly fibrous part of the atrial septum *fossa ovalis*. However, according to the authors, the diameter of the V-Clamp device is small enough to minimize this limitation (Pan et al. 2019b). To date, the clinical utility of the V-Clamp has been reported in only a few studies. Based on these, it can be optimistically assumed that their use will increase in the coming years. Since 2019, a team from the Department of Cardiology at Zhongshan Hospital, Fudan University in Shanghai, has successfully performed V-Clamp procedures as part of a program to evaluate the clinical utility of the device. The first trial brought together a group of 12 patients with degenerative MR, moderate to

severe and severe MR, with central stream due to A2 (in five patients) or P2 (in seven patients) prolapses, for whom mitral valve replacement surgery was too risky (Pan et al. 2019b). All patients achieved a MVR ≤2+, post-procedural orifice area ≥1.5 cm², and a transvalvular gradient <5 mmHg (Pan et al. 2019b). Importantly, the procedures took place over a short period, with an average of 26.8 ± 10.3 minutes passing from the time of apical puncture to suturing. Follow-up 90 days after surgery was also favorable. Eleven patients had MR1+, and one had MVR grade 2+ (with gradients ranging from 1.95±0.91 to 3.66±1.37 mmHg) (Pan et al. 2019b). One-year follow-up showed the possibility of atrial fibrillation, but this did not result in stroke in any of the patients. The severity of MVR varied significantly after one year, with some patients having no MVR at all, while one patient had an exacerbation to MR3+ with more severe P2 and P3 prolapse (Long et al. 2022). Overall, a statistically significant reduction in LV and LA remodeling was achieved after one year (Long et al. 2022). Significant MVR can also arise due to abnormalities in global or regional LV function or LV remodeling. MVR of this type is referred to as ventricular functional mitral regurgitation (VFMR). The results of treating VFMR with the V-Clamp have been compared with the efficacy of this method in patients with atrial functional mitral regurgitation (AFMR). The type of functional MVR had no adverse effect on the effect of the V-Clamp, and most patients (75%) had MR1+ postoperatively (Li et al. 2023). The report, which so far includes the largest number of patients (102 patients) with a one-year follow-up (CLAMP-2), confirms previous data on the utility of the V-Clamp as an effective method for treating both challenging degenerative and functional MVR (Pan et al. 2023). The CLAMP-2 study group consisted of 95% MR4+ patients. After treatment, about 60% had MR1+. The study also revealed a wider range of complications, including MV damage and device detachment within 30 days of surgery (Pan et al. 2023) (Table 2).

Interestingly, some patients with a flail gap of more than 10 mm and flail width of more than 15 mm were also successfully treated with a V-Clamp, while huge coaptation gaps are a limitation of the MitraClip (Ge et al. 2021b) (Fig. 3). However, a significant proportion of MRs are not central and originate from the A3/P3 region (Wei et al. 2017). There are few documented cases of A3/P3 clamping (Li et al. 2023), but single cases indicate this possibility. Residual MVR that arises secondary to the procedure may arise lateral to the clamping (A1/P1 and A3/P3). Residual MVR may be significant, and the placement of another clip should be considered. However, the mitral valve opening area must be greater than 3.5 cm², the mean transvalvular gradient ≤5 mm Hg, and the anterior and posterior leaflet lengths must exceed 10 mm at the site of regurgitation (Ge et al. 2021a). Additionally, when performing this procedure, special attention must be given to the LA wall to prevent damage (Ge et al. 2021a). While many procedures concluded with the application of a single clamp, some additional procedures were conducted as well. The vast number of procedures ended with a single clamp. In a review of 35 patients, a total of 37 clips were implanted (Ge et al. 2021b). Specifically, 33 patients received one clip each, while two patients received two clips. Additionally, in a recent study involving 102 patients, 13 were reported to have two clips placed (Pan et al. 2023).

Clinical study – Veterinary medicine

The first V-Clamp procedures on clinical canine cases were already performed in 2020 in China (Liu et al. 2020). Patients qualified for the procedure were characterized by stage B1 MMVD and a strong systolic murmur. The procedure performed resulted in reduced MVR in all patients, and at 3-month follow-up, only one patient was found to have residual, non-significant MVR. The effect of the V-Clamp on LV and LA remodeling in dogs has also been documented. Clamping in the A2/P2 position contributed to a slight reduction in LVIDDN and LA size (Kijtawornrat et al. 2024). Satisfactory results were obtained in a group of four dogs clamped in the A2/P2 position, in which the prolapses included A2 (Petchdee et al. 2024). A six-month follow-up showed a significant reduction in LVIDDN, LVIDs, and the LA/Ao ratio (Petchdee et al. 2024). Moreover, no serious complications related to the procedure were indicated. The largest clinical series of V-Clamp procedures in dogs to date (48 procedures) was performed at the Department of Clinical Sciences and James L. Voss Veterinary Teaching Hospital, College of Veterinary Medicine and Biomedical Sciences in the USA (Potter et al. 2024). All subjects undergoing clamping had MVR at A2/P2. Other non-central MRs were excluded from the study (Potter et al. 2024). MVR reduction varied significantly among individuals, which the authors attributed to their limited experience in performing this procedure. Consequently, the group of dogs that underwent the procedure last obtained the best results. Furthermore, two dogs exhibited a significant deterioration of the MVR after the procedure, and the decision to euthanize was made on this basis. In addition, several severe complications related to the procedure occurred, i.e., rupture of the head of the papillary muscle or detachment of the device (Potter et al. 2024). Interestingly, among the 48 dogs, as many as

Table 2. A summary of clinical trials and a comparison of them in terms of the results achieved and the complications that occurred in dogs.

Cause	Study group	Age (y.o.)	Nr.	Results	Complication	Follow-up	Source
stage B1 MMVD	Dog	5.8-7.2	8	- MR reduction - 12.5% residual MR	absent	- 100 to 141 days observation - total reduction of murmur (3msc) - MR absence	(Liu et al. 2020)
Stage B2, C, D MMVD	Dog	8.7-11.3	50	- 96% success rate in putting on a clip - MR reduction	- severe MR in two dogs (euthanasia) - sudden death the day after surgery - 3 cases of unlocking the clamp - detachment of the clamp from the posterior leaflet - idioventricular rhythm - premature ventricular syndromes - avulsion of the head of the posteromedial papillary muscle	- 1 Death due to heart failure 6 weeks after surgery	(Potter et al. 2024)
stage B1 MMVD	Dog	9	1	- residual MR	Absent	- 10 days - reduction LVIDDN and LA/Ao	(Kijtawornrat et al. 2024)
Stage B2, C	Dog	9-14	4	- residual MR	- nonsustained ventricular tachycardia	- reduction LVIDDN and LA/Ao (6 months)	(Petchdee et al. 2024)
MR3+/4+	Human	76.5 ± 6.3	12	- MR1+/2+	- atrial fibrillation	- 3 month mean orifice area reduction (from 4.34 ± 0.33 to 2.43 ± 0.58 ^{cm2})	(Pan et al. 2019b)
MR3+/4+	Human	74.26±6.41	35	- MR - height and volume of prolapse reduction (from 4.78±2.19 to 2.32±1.92 mm)	- mitral valve leaflet tear	absent	(Ge et al. 2021b)
MR3+/4+	Human	65-78	12	-MR1+/2+	- absent	- 3-month observation - LAD, LVEDD, LVESD reduction	(Li et al. 2023)
MR3+/4+	Human	76.5 ± 6.3	12	- MR1+/2+	- atrial fibrillation	- 1y observation - mean orifice area reduction (from 4.34 ± 0.34 cm^2 to 2.38 ± 0.45) - LAD reduction - LVEDD reduction	(Long et al. 2022)
MR3+/4+	Human	73.74 ± 6.43	102	- MR1+/2+	- disconnecting the device within 30 days - leaflet damage - to severe residual MR	- 1y observation MR1+/2+	(Pan et al. 2023)

nine had two clips inserted, and one had three implanted (Potter et al. 2024).

Clinical studies on dogs are limited by the fact that the performance of V-Clamp procedures for MVR of a different origin than valve leaflet prolapse has not yet been documented. Furthermore, previous reports on the use of these methods concern only central waves of regurgitation originating from A2P2 in dogs.

Conclusions

The Transapical Edge-to-Edge Transcatheter Mitral Valve Repair method in dogs has been in clinical trials for about 5 years. Scientists are expected to report on the effects of this observation soon. In veterinary medicine, it has gained a much broader application compared to humans, mainly due to fewer legal restrictions on its use. The V-Clamp has proven effective

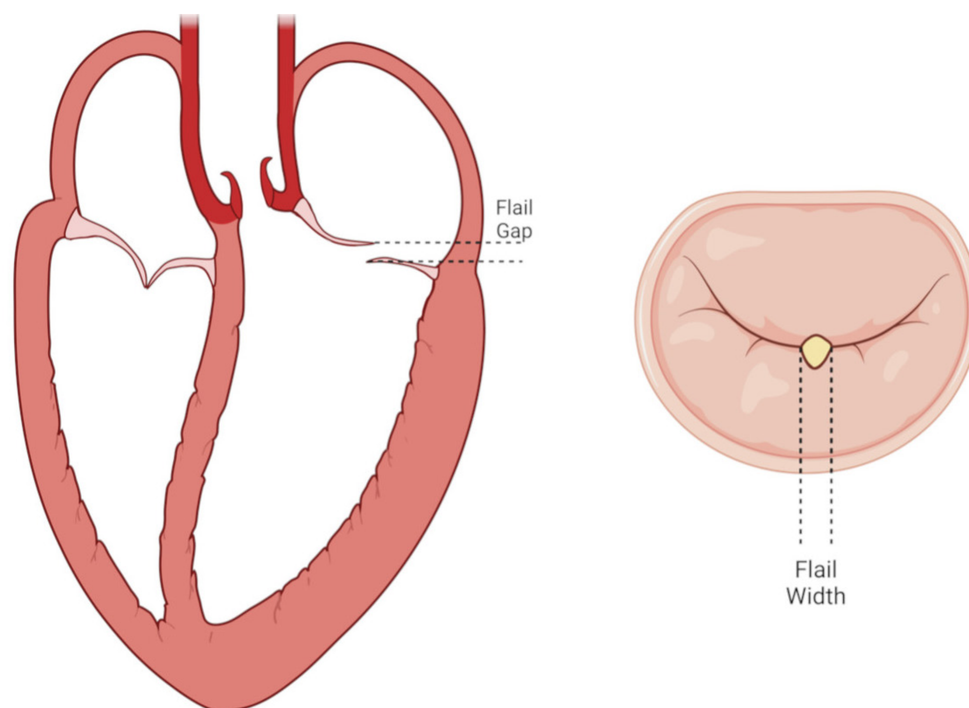

Fig. 3. Characteristics of flail scallops.

in reducing primary forms of MVR in dogs and humans, as well as functional MVR in humans. Clinical experience gathered from the widely used MitraClip system suggests that the key element determining the procedure's success is the correct patient qualification. It seems, therefore, that an important step when introducing the V-Clamp technology to veterinary medicine is to precisely define the group of patients in whom the use of this method can bring measurable therapeutic benefits. So far, dogs with mitral valve insufficiency secondary to prolapse of the A2 and P2 segments have been recruited. A key direction for further research will be to determine whether patients with other types of regurgitation can also benefit from the V-Clamp technique in a similar manner.

The introduction of the V-Clamp has undoubtedly initiated a breakthrough in minimally invasive veterinary cardiology, giving hope for effective mitral valve repair. It is likely, as in human medicine, that diversification of mitral valve repair methods will be necessary. Another key step in this direction would be to develop a device like the MitraClip, adapted to the needs of dogs, which would open up new perspectives in the treatment of mitral valve regurgitation in veterinary patients.

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Author declarations

Ethics approval

Ethics approval was not required for this article.

Use of generative artificial intelligence

Generative artificial intelligence was not used in the writing process or in the preparation of this manuscript.

Conflict of interest

The author declares no conflict of interest.

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