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Prevalence of major complications and procedural mortality in 336 dogs undergoing interventional cardiology procedures in a single academic center☆

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Abstract *Introduction:* Overall complication rates associated with a wide range of diagnostic and therapeutic interventional cardiac procedures in a contemporary academic setting have not been reported.
Animals, materials and methods: Consecutive interventional procedures performed for client-owned dogs were retrospectively analyzed to characterize procedural complications and mortality.
Results: Three hundred sixty-four procedures were performed on 336 dogs. Interventions included attempted or completed transvenous pacemaker (PM) implantation (n = 134) with subsequent pacing system revision (n = 8), pulmonic balloon

Abbreviations: ACDO, amplatz canine duct occluder; AVB, atrioventricular block; BVP, balloon valvuloplasty; CI, confidence interval; HW, heartworm; OR, odds ratio; PDA, patent ductus arteriosus; PM, pacemaker; PS, pulmonic stenosis; VSD, ventricular septal defect.

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valvuloplasty (BVP) (n = 117) with a subset of patients undergoing an additional BVP (n = 14), transarterial closure of left-to-right shunting patent ductus arteriosus (PDA) (n = 66), diagnostic angiography and/or cardiovascular pressure measurement (n = 9), transvenous temporary pacing (n = 7), septal defect occlusion (n = 5), heartworm extraction (n = 3), and BVP catheter fragment retrieval (n = 1). The prevalence of major perioperative and postoperative complications for all procedures was 5% and 6%, respectively, and the procedural mortality rate was 2%. The overall rate of major complications was 12% for the PM group, 11% for the BVP group, and 2% for the PDA occlusion group. Both PM implantation and BVP have higher rates of major complications overall compared with PDA occlusion (p=0.0151).
Conclusions: The results of this study indicate that the prevalence of major complications and mortality associated with interventional cardiac procedures is low; however, significant differences exist in complication rates between procedures.

Introduction

The indications for interventional cardiology procedures have evolved throughout the past several decades in veterinary medicine. Initially, the right- and left-sided cardiac catheterization techniques were published for experimental purposes in dogs undergoing research studies [1]. These techniques later evolved to encompass diagnostic and therapeutic aims for both congenital and acquired cardiac diseases [2]. While multimodal echocardiography has advanced to largely replace diagnostic catheterization in most instances, there are clinical scenarios where invasive cardiac catheterization provides salient diagnostic or prognostic information. Currently, minimally invasive interventional procedures are routinely performed in referral and specialty veterinary medical centers for therapeutic treatment of cardiac diseases in dogs [3]. The increasing frequency of interventional procedures has been chronologically influenced by technological advancements in devices and technique that has paralleled the increasing public demand for procedural proficiency in the interventional arena.

Common therapeutic indications for interventional cardiology in veterinary medicine include transvenous permanent artificial pacemaker (PM) implantation for bradyarrhythmias [4—10], balloon valvuloplasty (BVP) for severe or symptomatic valvular pulmonic stenosis (PS) [11—13], and transcatheter closure of patent ductus arteriosus (PDA) [14—17]. Less commonly performed interventional cardiac procedures include transcatheter closure of atrial and ventricular septal defects (VSDs) [18—20], balloon dilation for severe subaortic stenosis [21,22], balloon dilation of obstructive membranes such as cor triatriatum dexter [23—27] or tricuspid stenosis [28], and heartworm (HW) extraction [29,30]. While these interventional cardiology procedures are routinely undertaken at specialized veterinary centers in the current era, these procedures are not performed without calculated patient risks and benefits.

Rates of major complications associated with the commonly performed interventional cardiology procedures have reported to be reduced in the last 20 years [7,8]. However, to the best of the authors' knowledge, there has been no report in veterinary medicine focusing on overall complication rates and perioperative mortality associated with the wide range of interventional procedures performed in an academic cardiology program. Therefore, the primary aim of this study was to evaluate major complication rates associated with interventional procedures in dogs at a single academic center with a contemporary focus over the past decade. In addition, we sought to analyze each group of commonly performed procedures (BVP, PM implantation, and PDA occlusion) to provide updated information on major complications in dogs undergoing these procedures.

We hypothesized that patients who underwent BVP would have the highest rates of procedural mortality, particularly in smaller dogs with very severe PS. We hypothesized that dogs with Amplatz canine duct occluder (ACDO) implantation would have the lowest complication rates and mortality of the commonly performed procedures. We also hypothesized that dogs with a PM implant necessitating a PM revision procedure would have higher rates of major postoperative complications.

Animals, materials and methods

The medical records of client-owned dogs that underwent consecutive interventional cardiac

procedures between November 2005 and September 2017 at Oregon State University were retrospectively reviewed. Study enrollment was terminated in 2017 to ensure all included PM dogs had at least 6 months of follow-up due to the potential for delayed complications. All procedures were performed by a board-certified cardiologist or a cardiology resident under direct supervision of board-certified cardiologist. All dogs were hospitalized after each interventional procedure according to the institutional protocol for a minimum of 24 h. Dogs receiving PM implantation and BVP routinely undergo postoperative telemetry monitoring for a minimum of 12 h. The exclusion criteria included dogs with interventional procedures initiated elsewhere and subsequently referred to Oregon State University for revision procedures and dogs diagnosed with PDA who had aborted cardiac catheterization and were subsequently referred for surgical ligation.

Data retrieved from the medical record included signalment, weight, diagnosis, cardiac procedure performed, electrocardiogram diagnosis, response to atropine if performed, presence or absence of congestive heart failure, medications, presence of azotemia (blood urea nitrogen concentration $>$26 mg/dL or creatinine concentration $>$1.7 mg/dL), and Doppler-derived transpulmonic pressure gradient using peak flow velocity when available. Perioperative data collected included fluoroscopy time, duration of procedure, anesthetic score, incidence of hypotension under anesthesia (systolic arterial pressure $<$70 mmHg for at least 10 min), duration of anesthesia, and presence or absence of complications related to procedure. Postoperative data included total duration of hospitalization and presence or absence of complications related to procedure. Faculty cardiologists are present for all interventional procedures performed at this institution.

Perioperative and postoperative complications occurring over the study period were analyzed. Perioperative complications were defined as those occurring between premedication or procedure beginning and before complete anesthetic recovery. Postoperative complications were characterized as procedure-related complications that occurred after anesthetic recovery.

Perioperative and postoperative complications were further divided into major and minor complications. Major complications of PM implantation were defined as those considered to be life-threatening (e.g. sudden loss of implant pacing, ventricular fibrillation) or complications requiring a repeat procedure (e.g. lead dislodgement, lead or pulse generator infection, right ventricular perforation with failure to capture). Complications, including seroma formation, muscle twitching at the generator site, hemorrhage, arrhythmias that were responsive to pharmacologic therapy which did not result in aborting procedures (e.g. ventricular premature complexes), sensing problems, or minor anesthetic complications (e.g. hypothermia), defined as non—life-threatening were considered minor. Major complications of PDA occlusion were defined as life-threatening or requiring abortion of the procedure, which included cardiopulmonary arrest, device embolization, hemorrhage requiring transfusion, hemolysis, or vessel perforation. Minor complications included catheter site swelling, bruising, hematoma or seroma formation, and mild hemorrhage. Major complications of BVP included cardiopulmonary arrest, cardiac or vascular perforation, thromboembolization, and life-threatening arrhythmias causing abortion of the procedure. Inability to access the right ventricle during catheterization was considered a major complication of the BVP procedure. For the remaining procedures, major complications were those either potentially life-threatening or requiring abortion of the procedure; all other complications were classified as minor.

Statistical analyses were performed using commercially available statistical software package[c]. Descriptive data for age, weight, anesthetic and procedure times, fluoroscopy time, and duration of hospitalization are reported as median (range). Bimodal variables are reported as percentages. Descriptive rates of major perioperative and postoperative complications and overall complication rates, as well as mortality data, are presented in percentages and proportions.

Risk factors for major perioperative and postoperative complications, as well as the overall rate of major complications and dogs receiving BVP, were analyzed using generalized linear mixed models. A single (univariable) fixed factor or covariate for each risk factor was used for each model. A random intercept for each animal was included to model within animal correlation in animals with repeat procedures. A binary distribution with a logit link function was used. If the patient covariance estimate was 0, indicating that there was no within-patient correlation of complications, then alternatively logistic regressions with log-likelihood ratio test *p*-values were used to test risk factors.

[c] SAS V 9.3, Cary, NC.

For the PM and PDA groups, risk factors for major perioperative and postoperative complications, as well as the overall rate of major complications, were analyzed using simple logistic regressions. Log-likelihood ratio test *p*-values were used. If quasi-separation was present, Firth's bias-reduced penalized-log-likelihood ratio tests and odds ratios (OR) were used. If $p<0.05$ in the univariable analysis, then OR and 95% confidence interval (CI) were calculated. A significance threshold of 0.05 was used.

The following risk factors were assessed for significance for all dogs: age, sex, weight, syncope, heart failure, azotemia classification, fluoroscopy time, anesthetic score, anesthetic and procedural durations, presence of anesthetic hypotension, and duration of hospitalization. Specific risk factors assessed for PM dogs included indication(s) for PM implantation, atropine responsiveness, success of temporary transvenous pacing, and type of pacing lead implanted. A specific risk factor assessed for BVP dogs was the preoperative transpulmonic pressure gradient. The incidence of complications for these groups was also compared for procedural risk: PM, PM revisions, PDA occlusion, BVP, and additional BVP procedures.

Results

During the study period, 336 dogs had a minimally invasive interventional procedure attempted or completed. There were 310 dogs with a single procedure performed, and there were 26 dogs with more than one procedure performed, for a total of 364 procedures (Fig. 1). Descriptive patient data for each procedural group are detailed in Table 1. The prevalence of major perioperative and postoperative complications, as well as procedural mortality rates, is listed in Table 2. The details of procedural complications encountered are discussed in the following sections.

Transvenous PM implantation was attempted or completed in 134 dogs. The electrocardiogram diagnoses included third-degree atrioventricular block (AVB) in 80 (60%) dogs, sinus node dysfunction in 30 (22%) dogs, second-degree AVB in 18 (13%) dogs, and persistent atrial standstill in six (4%) dogs. Of the 61 dogs with an atropine response test performed and recorded, 27 (44%) dogs had complete or partial positive response and 34 (56%) dogs did not respond to atropine. The 27 dogs with a complete or partially responsive atropine test included 11 dogs with second-degree AVB, 10 dogs with sinus node dysfunction, and six dogs with third-degree AVB. The 34 dogs not responsive to atropine included 26 dogs with third-degree AVB, six dogs with sinus node dysfunction, one dog with second-degree AVB, and one dog with persistent atrial standstill.

Percutaneous temporary transvenous pacing through the jugular vein was successful in 129 (96%) dogs and either unsuccessful or not attempted in the remaining five (4%) dogs. Two dogs had transient loss of temporary transvenous ventricular pacing during the transition from the right to left lateral recumbency under general anesthesia; both dogs were repaced without incident using fluoroscopic guidance, so this was

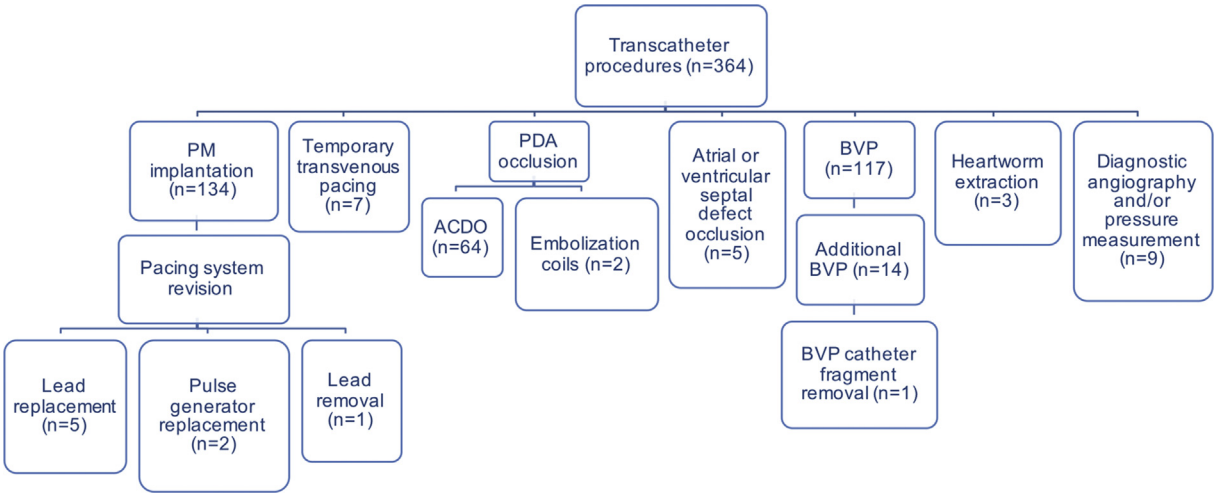

Fig. 1 Distribution of 364 procedures performed in 336 dogs. The number (n) in the figure refers to the quantity of procedures performed. ACDO, Amplatz canine ductal occluder; BVP, balloon valvuloplasty; PDA, patent ductus arteriosus; PM, pacemaker.

Table 1 Percentages and proportions (95% CI) of major complications for all procedures performed.

Procedure performed	Major perioperative complications	Major postoperative complications	Overall major complication rate	Procedural mortality rate
All procedures	19/364 = 5% (3–8%)	21/355[a] = 6% (3–9%)	40/364 = 11% (8–14%)	8/336 = 2% (1–5%)
Transvenous PM	3/134 = 2% (0–6%)	13/134 = 10% (5–16%)	16/134 = 12% (7–19%)	2/134 = 1% (0.2–5%)
BVP	12/131 = 9% (5–15%)	2/128[a] = 2% (0–5%)	14/131 = 11% (6–17%)	5/117 = 4% (1–10%)
PDA occlusion	0/66 = 0% (0–5%)	1/66 = 2% (0–8%)	1/66 = 2% (0–8%)	0/66 = 0% (0–5%)
Pacing system revision	0/8 = 0% (0–37%)	4/8 = 50% (9–76%)	4/8 = 50% (9–76%)	0/7 = 0% (0–41%)
Temporary transvenous pacing	0/7 = 0% (0–41%)	—	0/7 = 0% (0–41%)	0/7 = 0% (0–41%)
Diagnostic angiography	0/9 = 0% (0–37%)	0/9 = 0% (0–37%)	0/9 = 0% (0–37%)	0/9 = 0% (0–37%)
Septal defect occlusion	4/5 = 80% (28–99%)	0/5 = 0% (0–52%)	4/5 = 80% (28–99%)	0/3 = 0% (0–71%)
Heartworm extraction	0/3 = 0% (0–71%)	1/3 = 33% (1–91%)	1/3 = 33% (1–91%)	1/3 = 33% (1–91%)
BVP catheter fragment retrieval	0/1 = 0% (0–97%)	0/1 = 0% (0–97%)	0/1 = 0% (0–97%)	0/1 = 0% (0–97%)

CI, confidence interval; BVP, balloon valvuloplasty; PDA, patent ductus arteriosus; PM, pacemaker.
[a] Number of procedures (denominator) is reduced to reflect dogs that died intraoperatively, as well as with temporary PM patients who were not included in the postoperative complication analysis. Values are rounded to the nearest whole percent.

considered a minor complication. A single passive ventricular lead was implanted in 93 (69%) dogs, and a single active ventricular lead was implanted in 40 (30%) dogs. No dogs had more than a single ventricular lead implanted at our institution.

The most common major perioperative complication consisted of ventricular fibrillation in three dogs after transvenous temporary pacing had commenced; two dogs were successfully resuscitated and one dog was unable to be resuscitated. Two of these dogs had third-degree AVB and one dog had sinus node dysfunction. Major post-operative complications occurred in 13 dogs; these complications included intermittent or complete capture failure without lead dislodgement in four dogs, lead dislodgement in three dogs, followed by single instances of battery migration, pacing system infection, right ventricular perforation, lead insulation break, cardiopulmonary arrest, and severe aspiration pneumonia. Of the four dogs with capture failure without lead dislodgement, one dog had intermittent capture failure documented immediately postoperatively after endotracheal extubation with brachycephalic syndrome and capture loss that was phasic with deep inhalation. Lead repositioning was performed and extra slack was added to the pacing system, which resolved the intermittent capture failure. No apparent cause of the capture loss was evident for the remaining three dogs with high capture thresholds and normal impedance. Of the three dogs with lead dislodgement, one occurred during the immediate postoperative period and the other two dogs had lead dislodgement several weeks after PM implantation; two of these dogs originally had a passive lead and the third dog originally had an active lead implanted. The dog with an infected pacing system had several underlying endocrinopathies with resultant dermal thinning and erosion of the cervical subcuticular suture material. The dog with migration of the pulse generator occurred approximately 4 years after implantation without an antecedent event; this dog's pulse generator had been sutured routinely using 0-Prolene in the subcutaneous caudodorsal cervical region. The dog with the right ventricular perforation had this occur three months post-operatively; she was a large breed dog with an active fixation lead. The dog which arrested four hours post-operatively was suspected to have cardiopulmonary arrest due to respiratory depression associated with injectable opioids and concurrent severe brachycephalic syndrome based on telemetry review and relevant necropsy findings.

Of the seven dogs that subsequently had pacing system revisions, five dogs had the pacing lead replaced or repositioned, and two dogs had a battery change after migration or depletion of the initial battery. Both dogs with pulse generator revisions developed major postoperative

Table 2 Descriptive data by interventional groups.

Group	Age (yrs)	Wt (kg)	Sex (n)	Common breeds (n)	Syncope (n),%	HF (n),%	Concurrent heart disease (n)	Anesthetic time (mins)	Anesthetic hypotension (n),%	Procedure duration (mins)	Fluoro time (mins)	Hosp duration (days)
PM (n = 134)	10 [0.75–15]	17.8 [2.7–52.2]	SF (73), CM (51), F (4), M (6)	Labrador retriever/mix (21), Miniature schnauzer (17), German shepherd/mix (9), Dachshund (8), Cocker spaniel/mix (8), West Highland terrier (5)	(82), 61%	(16), 12%	CDVD (18), TVD (1)	187 [25–467]	(77), 57%	128.5 [30–246]	5 [1–31]	1 [0–15]
BVP (n = 117 dogs, 131 procedures)	0.75 [0.25–6.5]	9.0 [2.4–50]	SF (9), CM (30), F (29), M (49)	French bulldog (17), Pitbull (13), Chihuahua/mix (14), Cavalier King Charles spaniel (7), Pomeranian (6), Miniature schnauzer (5), German shepherd/mix (4)	(14), 12%	(8), 7%	VSD (3), TVD (2), CTS (1), PDA (1), MVD (1), PFO (1), ASD (1), ASD + VSD (1), ASD/PFO + PLCVC + double caVC (1), TVD + SAS (1), VSD + aortic root deviation + coronary artery anomaly (1)	150 [74–279]	(93), 71%	92 [21–20]	17 [1–48]	1 [0–6]
PDA occ-lusion (n = 66)	0.79 [0.17–13]	10.6 [2.7–38]	SF (22), CM (8), F (26), M (10)	German shepherd/mix (8), Pembroke Welsh corgi (7), Labrador retriever (7), Border collie (5), Newfoundland (3)	(1) 2%	(17) 26%	SAS (2), PS (1)	196 [119–405]	(43) 65%	119.5 [46–200]	7 [3–26]	1 [1–3]
Pacing revision (n = 7 dogs, 8 proc-edures)	6 [4.5–14]	26.5 [5.2–40]	SF (5), CM (1) M (1)	Single dogs of various breeds	(3) 43%	(0)	CDVD (5)	198.5 [71–337]	(5) 63%	119 [54–186]	4 [0–51]	1.5 [0–5]
Temp pacing (n = 7 dogs)	11 [0.6–16]	7.9 [3.6–20]	SF (4), CM (2), F (1)	Single dogs of various breeds	(1) 14%	(1) 14%	CDVD (2), bi-ventricular dysfunction (1)	NA	NA	—	1.5 [1–14]	NA
Diag-nostic angio-grapy or pressure meas-urement (n = 8 dogs, 9 proc-edures)	0.6 [0.16–8]	12.7 [1.8–35.5]	SF (2), CM (1), F (3), M (2)	Single dogs of various breeds	0	(1) 14%	Anomalous aorto-pulmonary connection (1), PRAA (1), DCRV (1), PS + R2A (2), hepatic vascular anomaly (1), DCM + lungworm (1)	120 [59–345]	(4) 50%	78.5 [36–126]	7.5 [2–11]	2 [1–10]
Septal defect occlusion (n = 3 dogs, 5 proc-edures)	1.1 [0.6–2]	4.8 [4.7–45]	SF (1), M (2)	Single dogs of various breeds	0	(1) 33%	PS (2)	261 [170–375]	(4) 80%	135 [105–315]	51 [24–65]	2 [1–2]
HW removal (n = 3 dogs)	4 [4–8]	5.4 [4.5–21.4]	SF (1), M (2)	Single dogs of various breeds	(1) 33%	0	Caval syndrome with cor pulmonale (3)	122.5 [105–140]	(1) 33%	87.5 [75–100]	12 [6–44]	0.5 [0–1]

For procedural analyses (anesthetic time, incidence of anesthetic hypotension, procedure duration, and hospitalization time), data from all dogs undergoing each procedure were used. For patient demographic information (age, weight, sex, breed, presence of syncope, presence of heart failure, and concurrent heart disease) only a single entry was used for each dog to eliminate redundant data. Data are provided as median and [range], or (number) and percentage.

ASD, atrial septal defect; BVP, balloon valvuloplasty; caVC, caudal vena cava; CDVD, chronic degenerative valve disease; CM, castrated male; CTS, cor triatrum sinister; DCM, dilated cardiomyopathy; DCRV, double chamber right ventricle; F, female; fluoro, fluoroscopy; HW, heartworm; hosp, hospitalization; M, male; mins, minutes; MVD, mitral valve dysplasia; PM, pacemaker; PDA, patent ductus arteriosus; PFO, patent foramen ovale; PLCVC, persistent left cranial vena cava; PRAA, persistent right aortic arch; PS, pulmonic stenosis; SAS, subaortic stenosis; SF, spayed female; temp, temporary; TVD, tricuspid valve dysplasia; VSD, ventricular septal defect; wt, weight.

complications consisting of pacing system infections; one infection was documented 4 weeks after battery replacement and the other dog had a chronic draining tract diagnosed 16 months after battery replacement. Both these dogs had an epicardial system implanted after the infected battery was removed and the endocardial PM lead severed close to the thoracic inlet. One of these dogs later required extraction of the abandoned endocardial PM lead, which was performed without major complication [31]. Two of the five dogs with a PM lead replacement or repositioning experienced an additional major postoperative complication, consisting of an insulation break 1-month after revision in one dog and capture failure 2 years after revision in another dog.

One hundred seventeen dogs had an attempted or completed BVP for PS; 14 dogs had an additional BVP for a total of 131 BVP procedures. All dogs had severe ($\geq$80 mmHg) or symptomatic PS; the median preoperative transpulmonic pressure gradient was 144 mmHg (range, 78–320 mmHg). Access was obtained by jugular vein catheterization in all dogs except one with a persistent left cranial vena cava and absent right cranial vena cava who had femoral vein catheterization. Balloon inflation occurred by hand in all dogs using a balloon to annulus ratio of 1.2–1.5. Of the 11 dogs with major perioperative complications, all dogs had a single major complication except one dog which experienced two major perioperative complications. These complications include cardiopulmonary arrest (n = 4), malignant ventricular tachycardia refractory to pharmacologic treatment (n = 3), cardiac perforation with resulting pericardial effusion (n = 2), balloon rupture with pulmonary arterial fragment embolization (n = 1) or jugular venous embolization (n = 1), and inability to access the right ventricle with concurrent tricuspid valve stenosis (n = 1). Of the four dogs that had cardiac arrest, one developed asystole after several balloon inflations and was successfully resuscitated, one developed severe hypotension after balloon inflation that progressed to ventricular fibrillation that was not successfully resuscitated, one dog became severely bradycardic after an unremarkable BVP just before anesthetic recovery and was not successfully resuscitated, and the final dog had a cardiac perforation followed by cardiac arrest with unsuccessful resuscitation. Two of the three dogs that had the BVP aborted due to refractory ventricular tachycardia had an additional successful BVP 1 month later. An additional dog with cardiac perforation had the procedure aborted with resolution of pericardial effusion postoperatively; the patient had an uncomplicated successful BVP 1 month later. Interestingly, the two dogs that developed pericardial effusion had this complication occur during the catheterization procedure before balloon inflation. Two BVP dogs had major postoperative complications: one dog was euthanized due to severe aspiration pneumonia and the other dog experienced suspected sudden cardiac death immediately following hospital discharge after routine BVP and uneventful recovery period.

Sixty-six dogs underwent PDA closure using an ACDO device (n = 64) or non-detachable embolization coils (n = 2). The procedure was aborted in eight additional dogs weighing 2.7–6.3 kg, where the femoral artery was unable to accommodate the requisite delivery sheath, and these dogs were excluded from further analysis. Five (7%) dogs had documented pathologic preoperative arrhythmias consisting of atrial fibrillation (n = 2), ventricular arrhythmias (n = 2), and supraventricular premature complexes (n = 1). There were no major perioperative complications and one major postoperative complication in this population, consisting of ACDO dislodgement in a German shepherd dog within 1 month of implantation. Thoracic radiographs indicated the ACDO had migrated into the right caudal pulmonary artery, and the dog was asymptomatic for both the PDA and the embolized ACDO. The authors attempted to use an ACDO with the waist being double the measured size of the minimal ductal orifice diameter; the dog with the dislodgement had a slightly undersized ACDO waist to minimal ductal diameter of 1.75.

Eight dogs underwent diagnostic catheterization for angiography and/or cardiovascular pressure measurement; one dog had two diagnostic angiographic catheterizations. No major perioperative or postoperative complications occurred in any of the dogs in this group.

Seven dogs had a temporary transvenous pacing using a bipolar pacing catheter through a percutaneously placed right jugular introducer for anesthetic stability. These include dogs undergoing anesthesia for an epicardial PM (n = 3), oncologic surgery (n = 2), cystotomy (n = 1), and enucleation (n = 1). Four dogs had sinus node dysfunction and three had third-degree AVB. There were no major perioperative complications associated with temporary pacing; the pacing lead was removed uneventfully postoperatively in all dogs. Postoperative complications for this group were not included in our analysis, as postoperative patient decision-making was under the domain of the Oregon State University surgery service.

Two dogs both underwent two procedures for minimally invasive closure of large muscular VSDs. All four procedures resulted in major perioperative complications: one dog had ventricular tachycardia followed by cardiac arrest during both procedures but was resuscitated each time and had successful implantation of a muscular VSD occluder device after BVP [18]. The second dog had the procedure aborted twice; the first attempt resulted in stenting of the RV by a relatively stiff VSD occluder delivery sheath with resultant hypotension and an electrically unstable sinoventricular rhythm. The second attempt resulted in acute hypovolemia and mediastinal hemorrhage due to a suspected vascular perforation. No postoperative complications were noted in either dog. A third dog in this group had atrial septal defect occlusion attempted with no major complications noted.

Transvenous HW extraction was performed in three dogs with caval syndrome using Ishihara HW extraction forceps. No major perioperative complications were documented. One dog had a fatal complication in the immediate postoperative period consisting of cardiopulmonary collapse, massive pulmonary edema, and death.

Risk factor analysis

Perioperative complications

For the three commonly performed procedures (e.g. primary PM implantation, BVP, PDA occlusion), there were significant differences in rates of major perioperative complications ($p=0.0056$). The BVP group had greater perioperative risk for major complications than either PDA occlusion (OR 13.9 [1.9->1000]) or PM implantation (OR 3.9 [1.3−15.6]). Dogs with PM implants had more risk of major perioperative complications than PDA occlusion (OR 3 [0.3−500]). No significant differences in perioperative complications were present comparing initial BVP with additional BVP ($p=0.5715$) or comparing primary PM implantation with PM revisions ($p=0.8392$). The risk of major perioperative complications was significantly increased in dogs with syncope for BVP procedures ($p=0.0438$, OR 4.4 [1.1−16.7]) in the univariate analysis. There was no factor that was significantly associated with major perioperative complications for the PM and PDA groups.

When evaluating all the procedures performed, the risk of major perioperative complications was increased in dogs with lower body weights ($p=0.0533$) and in dogs with longer fluoroscopy times ($p=0.0002$) in the univariate analysis. When body weights and fluoroscopy times were entered into a multivariate model, only fluoroscopy time ($p=0.0006$, OR 1.07 [1.03−1.1]) remained significantly associated with major perioperative complications.

Postoperative complications

There were significant differences in risk of major postoperative complications between the commonly performed procedures ($p=0.0336$). The risk of major postoperative complications was lower in BVP patients compared with PM patients (OR 0.15 [0.03−0.8]) and PDA patients (OR 0.14 [0.02−1.4]). The risk of having a major postoperative complication was higher for PM revisions compared with the primary PM implant ($p=0.0041$, OR 5.6 [1.1−25.6]). The risk of major postoperative complications was significantly increased in younger dogs with PM implantation ($p=0.0443$, OR 0.85 [0.73−0.996]) in the univariate analysis. No other variables reached significance in the univariate analysis for the three commonly performed procedures; therefore, multivariate analysis was not performed.

For all procedures performed, the risk of major postoperative complications was significantly increased in dogs with syncope ($p=0.0118$, OR 3.8 [1.4−10.5]) in the univariate analysis. No factors were significantly associated with major postoperative complications in the multivariate analysis; however, there was a significant association of syncope with sex, which would invalidate the independent assumption of risk factors in multivariate analysis.

Overall complications

For the three commonly performed procedures, there were significant differences in risk for overall major complications between procedures ($p=0.0151$). Compared with PDA occlusion, there was higher risk associated with PM implantation (OR 10 [1.1−50]) and BVP (OR 7.8 [1−60.5]). There was slightly lower risk for BVP compared with PM implantation (OR 0.9 [0.4−1.9]). There was no significant difference in risk for overall complications between the primary PM implantation and PM revision ($p=0.0751$) or initial BVP and additional BVP ($p=0.7320$).

For all procedures performed, the risk of major complications overall was significantly increased in dogs with syncope ($p=0.0276$, OR 2.3 [1.1−4.9]), as well as dogs with longer fluoroscopy times

(p=0.0083, OR 1.04 [1.01−1.07]). Furthermore, both factors remained as significant risk factors for all procedures in the multivariate model (syncope p=0.0054, OR 3.2 [1.5−7.1], fluoroscopy time p=0.0016, OR 1.06 [1.02−1.09]).

Discussion

Minimally invasive interventional procedures performed by veterinary cardiologists carry calculated risks and benefits to veterinary patients. While several retrospective studies have reviewed the complication rates associated with the commonly performed interventional procedures, the present study provides a contemporary perspective that encompasses the procedural diversity that academic cardiologists encounter at one institution with a moderate interventional caseload.

In the present study, the prevalence of major complications overall was 11% for all interventional procedures. The procedural mortality rate was 2% for all procedures. While no correspondent veterinary study exists for direct comparisons, a North American study evaluating 11,821 cardiac catheterization procedures in people at a single center indicated an overall complication rate of 15.1% and 3.6% for therapeutic and diagnostic procedures, respectively [32]. In the same study, procedure-related mortality rates were 0.5% for therapeutic and 0.1% for diagnostic procedures. This discrepancy in mortality from human to veterinary medicine is likely due to greater operator experience and stronger personnel skills of human interventional teams in large-volume interventional centers.

Our analysis provided valuable insight regarding relative procedural risk. Both PM implantation and BVP have higher rates of major complications overall compared with PDA occlusion. This is logical as patients undergoing PDA occlusion with an ACDO tend to have minimal procedural complications at our institution, given the current ease of access, device sizing, and deployment of ACDOs. The overall complication rate was higher in dogs with longer fluoroscopy times; the complication rate increased by 6% for every minute of fluoroscopy used. We suspect the risk associated with increased fluoroscopy time is a reflection of interventional procedures that proceed with difficulty. In other words, this finding is likely a direct result of the complication rather than a contributor to the complication itself. It is also possible that longer fluoroscopy times associated with difficult procedures carry more anesthetic risk. In addition, dogs with preoperative syncope were at increased risk for major complications overall, as well as postoperative complications. This finding may be due to the combined effects of BVP and PM patients with more advanced disease who are syncopal and subsequently higher risk candidates for interventional procedures.

When major complications were divided into perioperative and postoperative categories, certain procedures were more likely to have a major complication. The BVP group had higher rates of major perioperative complications compared with PM and PDA patients. This reflects the fact BVP procedures have greater risk of perioperative complications, where PM patients generally have more postoperative complications. There was also increased risk of major complications associated with younger dogs receiving a PM and patients receiving a PM revision, which are likely related to each other. Most PM patients are older and, therefore, inevitably have less time to develop pacing system complications, whereas younger PM patients are more likely to require a PM revision surgery at our institution.

Several large-scale retrospective studies have reviewed the procedural outcomes and complication rates of the commonly performed interventional procedures in veterinary medicine. For transvenous single-chamber PM implantation, rates of major complications have steadily decreased over the decades. Life-threatening major complications were initially 42−55% in the 1980s [6,33], which decreased substantially over the next decades to 13−43% [4,5,7,9,34], to more recently be 13−18% [8,35]. While these studies have variable classification schemes for major and minor complications, the overall trend is likely valid. The results of our study are consistent with more recent PM outcome literature, with an overall institutional major complication rate of 12% [8,35]. Looking forward, it is theoretically possible that the rate of major complications will continue to decline with advancements in technique and equipment.

The distribution of major PM-related complications in our study is similar to the reported studies, particularly with lead dislodgement being one of the most common complications occurring in the first days to weeks after implantation [8]. However, even more prevalent in our population was PM capture failure with high voltage requirements and normal impedance. In the absence of drugs or electrolyte abnormalities that could raise pacing thresholds, or radiographic evidence of pacing system malfunction, considered differentials

include damage at the electrode—myocardium interface such as exit block or infiltrative myocardial disease [36]. Less likely differentials such as lead fracture, insulation break, chamber perforation, or hardware connectivity malfunction will generally have attendant changes in impedance.

Interestingly, our data suggested frequent major postoperative complications occurred in the PM revision group, although this group was composed of a small number of dogs. There was also increased risk of major complications for younger PM patients, who more frequently required a revision procedure. When accounting for primary PM implantations and PM revision procedures together, our institutional infection rate is acceptable (2%) and is similar to contemporary infection rates reported in humans with implantable cardiac devices [37,38] and dogs in an optimized research setting [39]. Both dogs receiving a pulse generator change in our fluoroscopy laboratory developed pacing system infections. Empiric broad-spectrum perioperative and postoperative antibiotics were used in these cases according to the institutional protocol. While the incidence of device infection is underpowered within our study to make absolute conclusions, adequately powered studies of human PM patients have found that PM revision procedures are two to four times greater risk for infection [38,40,41]. There are numerous patient, personnel, and operator factors to be considered when analyzing infection risk [42], and human guidelines for management of implantable cardiac devices recommend generator changes should be performed or supervised by experienced operators in an appropriately ventilated room to mitigate the increased risk of infection compared with primary implants [43]. This emphasizes that the consequences of PM revision can become more serious than the initial complication.

With regard to the BVP group, our study results indicate there were more frequent major perioperative complications (9%) than postoperative complications (2%), which is consistent with another veterinary study with an overall major complication rate of 14% [44]. Our procedural mortality rate was 4%, which is similar to other contemporaneous studies in dogs undergoing BVP with reported procedural mortality rates of 2—8% [11,12,44,45]. This finding confirms our hypothesis that BVP performed at our institution has the highest mortality rate of the commonly performed procedures. Complications during human BVP are remarkably rare with a reported 0.35% major complication rate and 0.24% mortality rate in 822 cases from 25 institutions with infant, child, and adult patients [46]. Major complications reported in that study included cardiac perforation with resulting tamponade or annular and venous tears; arrhythmias requiring resuscitation and respiratory arrest were classified as minor complications, which would be classified as major complications in our study so direct comparisons between studies are limited for multiple reasons.

Patients in our study with one or more episodes of preoperative syncope before BVP were at increased risk for perioperative complications and major complications overall. This finding substantiates prior studies in dogs undergoing BVP, with one study indicating that dogs with clinical signs at presentation had a 16-fold increase in risk of death compared with asymptomatic dogs [45]. This finding is likely due to the fact that more severely affected PS patients tend to be symptomatic either from inadequate cardiac output or pathologic arrhythmias and are consequently higher risk BVP candidates. We also noted frequent anesthetic hypotension in our BVP population, which has been previously reported commonly in BVP patients [12] and may be related to anesthetic technique (e.g. myocardial depressant effects of anesthetic drugs, bradycardia, vasodilation), poor cardiac performance secondary to severe PS, or a combination of both factors. Another study evaluating anesthetic complications during BVP found that 28% of dogs had systemic arterial pressures $\leq$70 mmHg for at least 10 min [12]. We also had two BVP catheters rupture: one catheter that lodged in the proximal external jugular vein was successfully retrieved by surgical cutdown and the other catheter was not successfully retrieved after a catheter fragment migrated to the right pulmonary artery with attempted retrieval occurring during a separate anesthetic event from the BVP. Fragments of ruptured catheters were not retrieved in another study with no apparent adverse consequences [12].

With regard to PDA occlusion, rates of major complications for transcatheter closure have decreased with use of the ACDO [15—17]. The ACDO has become the treatment of choice in eligible patients because of low complication rates and complete occlusion compared with other transcatheter methods or surgical ligation. In recent studies, the rate of major complications in dogs undergoing ACDO implantation was 3—8% [15,17], which is consistent with our overall major complication rate of 2% and our procedure-related mortality rate of 0%.

The overall rate of major complications for attempted atrial or VSD closure in our study was high

at 80%. There are single-case reports [18,20,47] and one case series [19] describing techniques and challenges encountered in dogs undergoing septal closure, which underscores the infrequent nature of atrial or ventricular septal occlusion by veterinary cardiologists. One study reported major complications in 24% of dogs undergoing atrial septal defect occlusion with device embolization occurring most commonly [19]. In human medicine, patients undergoing transcatheter VSD closure also experience relatively frequent procedural complications with residual shunting (25.5%), arrhythmias (10.6%), valvular incompetence (4.9%), and device embolization (0.4%) reported [48]. Mortality rates range from 0 to 8% according to one meta-analysis [48]. Furthermore, one human study also found that smaller patients (<5 kg) had increased procedural risk or device-related complications during transcatheter VSD closure [49]. In our study, both dogs undergoing VSD closure were small breed dogs, and VSD closure is infrequently performed at our institution; both factors may provide reasonable justification to explain the higher complication rate.

The overall rate of major complications for HW extraction was 33.3%; however, owing to very small sample size, these data should be interpreted cautiously. There is low prevalence of caval syndrome in our geographic region and relatively low operator experience with HW extraction. Nonetheless, our overall results are similar to the reported mortality rate of 29% associated with HW extraction in one study of 21 dogs [29], where two died intraoperatively and four died postoperatively.

Several limitations need to be considered when interpreting the results of this study. The most important limitation is the retrospective nature of the study; results are limited by the accuracy of patient records. To mitigate this inherent limitation, we specifically targeted parameters that were consistently recorded in the medical records. Information that was less reliably documented (i.e. minor complications) was recorded but not analyzed for statistical significance due to inconsistent documentation. Another limitation is that we did not categorize BVP patients by the presence and/or severity of pulmonic hypoplasia. The authors feel that dichotomous categorization of dogs with PS by the degree of commissural fusion with valve leaflet thickening or pulmonic annular dysplasia may oversimplify a wide morphologic spectrum of disease. Finally, our study did not include newer interventional procedures such as stenting, intravascular embolization, or chemotherapeutic targets [50] or procedures where the primary interventional operators are not cardiologists (e.g. intrahepatic portosystemic shunt occlusion), so results are limited to our institution.

Conclusions

In conclusion, the complication rates in this study were similar to those reported in contemporaneous veterinary studies. The procedure-related mortality rate in this study was low. The rates of major complications overall were significantly greater in PM and BVP patients in our population. There was also greater procedural risk for major complications in BVP and PM patients, particularly in young PM patients and syncopal BVP patients.

Conflict of Interest Statement

The authors do not have any conflicts of interest to disclose.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jvc.2019.01.003.

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