Outcome clinical audit: analyses of interventional closure of patent ductus arteriosus in dogs

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Abstract:	Abstract Objectives The objectives of this study were to determine whether conducting a clinical audit was achievable in a group of centres that perform interventional cardiac procedures and to report the success and complications rates in dogs diagnosed with patent ductus arteriosus (PDA). Methods This was a multi-centre, European-wide, prospective study. Patient data were entered into a bespoke database prior to commencing interventional closure of PDA in all animals undergoing this procedure during the study period. The database was designed to gather clinical audit information, after completion of the procedure, such as discharge outcome, complication rate and medium-term outcome. Results A total of 339 cases were included from five participating centres. The process of performing clinical audit was achieved in all centres. Successful discharge outcome was 95.9% with a complication rate of 4.1%. The procedure-related mortality was 0.6%. 149 cases (43.9%) were either lost to follow-up or had not yet had a follow-up within the time period. Of the remaining 169 cases in which follow-up was available, 157 (92.9%) had a successful medium-term outcome Conclusions This study demonstrates that the process of performing a clinical audit is achievable in veterinary clinical interventions across different centres. These results provide a benchmark for future comparison in our ongoing clinical audit and validate the process of clinical audit for other centres performing cardiac interventions. The use of clinical audit should be considered in other aspects of veterinary medicine.
Response to Reviewers:	

Outcome clinical audit: analyses of interventional closure of patent ductus arteriosus in dogs

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Running head: Clinical audit in interventional cardiac procedures

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List of Abbreviations

ACDO – Amplatz Canine Duct Occluder

AVP2 – Amplatzer Vascular Plug 2

CHF – congestive heart failure

Fr – French

IQR - interquartile range

mGy - milliGray

PDA – patent ductus arteriosus

TOE – transoesophageal echocardiography

Study centres:

CPH - University Hospital for Companion Animals, Copenhagen, Denmark

EDN - University of Edinburgh Royal (Dick) School of Veterinary Studies, Scotland

HVT - HeartVets, England

OSL - AniCura Oslo Animal Hospital, Norway

WLS - Willows Referral Centre, England

Introduction

Clinical audit remains in its infancy in veterinary medicine, but is an emerging aspect of clinical governance (https://vetaudit.rcvsk.org/). Clinical papers in veterinary journals are dominated by research that documents new knowledge, often following randomisation of differing cohorts, with the aim of progressing and evolving novel methods or techniques. By contrast, clinical audit aims to measure standards of care or service set by that research and to monitor established techniques or processes to ensure they are working as expected. Research typically requires ethical approval whereas clinical audit does not [1].

Clinical audit has been in place for surgical and interventional cardiac procedures in human medicine for over 30 years. Since 1988, the British Cardiovascular Interventional Society has been collating outcome data for consultant cardiologists who perform percutaneous coronary intervention in the United Kingdom [2]. Their aim was to create a registry of all percutaneous coronary intervention procedures to assess quality of care, drive improvements and provide a benchmark. The first publication of their findings was in 1990 [3]. In 2011 management of the British Cardiovascular Interventional Society registry was moved to the National Institute of Cardiovascular Outcomes Research (https://www.nicor.org.uk/about-nicor/) [4]. The results and reports from this audit (https://www.bcis.org.uk/public-reports/), as well as individual outcomes data, are viewable in the public domain. Outcome clinical audit monitors the success and complication rates of an established technique or procedure. If audit is used appropriately and efficiently, it can be an effective tool for improvement. Or, put more simply, audit helps to find out whether or not a method or process is attaining an established standard, with the potential to drive further

improvements in outcomes. Analyses with implementation of improvements and subsequent re-audit are important features of the clinical audit cycle.

As interventional procedures become more commonplace in veterinary cardiology, audit becomes an important tool to assess current clinical standards, or as a means of benchmarking for new centres and individuals embarking on interventional procedures.

Interventional closure of PDA in dogs is now well-established [5–7] and is offered by an increasing number of specialist centres. However, within this relatively new but fast-growing field, individual centres may evolve their procedural techniques and processes differently, with different associated complications. Therefore there is a need to perform an audit in order to share the details of those methods along with their complication rates and to help improve the collective standards.

The primary objective of the study was to determine whether conducting a clinical audit was achievable in a group of centres performing interventional cardiology. Secondary objectives were to provide benchmark data for success and complication rates, using the procedural techniques and processes described by our centres for PDA closure.

Materials and Methods

This was a multicentre prospective study involving five cardiology referral centres in Europe: Willows Referral Centre, England (WLS), HeartVets, England (HVT), University of Edinburgh Royal (Dick) School of Veterinary Studies, Scotland (EDN), University Hospital for Companion Animals, Copenhagen, Denmark (CPH), AniCura Oslo Animal Hospital, Norway (OSL). Data was collected from November 2015 to April 2021. The lead author (MM) had significant input in interventional training in all centres except EDN.

All dogs were client-owned, had been diagnosed with a PDA and were scheduled for interventional device closure. Written consent was given by all owners and comprehensive physical and echocardiographic examinations were performed by a Diplomate in cardiology or resident under supervision. Where indicated by the presence of clinical signs or cardiomegaly on echocardiography, thoracic radiographs were performed at the discretion of the clinician. Echocardiographic measurements of the PDA diameter at the levels of the ostium (sometimes termed the minimal ductal diameter) and ampulla (in the location of where a device would be implanted) were made prior to the procedure [8,9].

Clinical Audit database

Patient data of all consecutive cases intended for PDA interventional closure were included. Participating centres entered their data, during the patient preparation time prior to the procedure, into a bespoke database using Microsoft Excel spreadsheet [h]. The primary objective of the database design was that it was quick and easy to

complete, and the outcomes simple to enter at the time of the post-intervention examination, prior to discharge.

Data recorded included: date, patient identification, breed, age, body weight, initials of the lead interventionalist, discharge outcome, complications, medium-term outcome, total radiation and additional comments (Fig. 1).

Discharge outcome had a binary entry of either 1 (yes) or 0 (no) using the following definition: at the time of recovery and discharge from of the hospital, there had been a successful procedure and closure of the PDA with no more than trivial residual PDA flow using criteria previously described [10], on a post-procedural echocardiographic examination within 24 hours of the procedure. Above this column heading for successful discharge outcome was a percentage (%), which would automatically update with each new case entry.

Complications had a binary entry of either 1 (yes) or 0 (no) using the following definition: clinically significant event during the procedure, needing some form of clinical intervention/treatment such as any complication resulting in a clinical decision to abort the procedure, any complication that led to death in the peri-interventional period or in the following few days, dislodgement/embolisation of the device, ventricular fibrillation needing defibrillation, significant lameness, device infection or thrombus formation, rupture or tearing of a vessel resulting in haemorrhage or failure to cannulate the access vessel.

Medium-term outcome had a binary entry of either 1 (yes) or 0 (no), or could be left blank if not yet obtained, i.e. follow-up was still pending. The definition of successful medium-term outcome was: device in place and dog not in congestive heart failure

(CHF) and not needing cardiac medications in the following three-to-12 month period with no ongoing clinical signs.

Above the column headings for discharge outcome, complication and medium-term outcome, the percentage (%) total was displayed, which would automatically update with each new case entry (ignoring blank cells where appropriate).

Total radiation was recorded as total radiation dose and/or time, depending upon the centre's facilities, provided by the image-intensifier software. Total radiation dose in milliGray was a combination of radiation dose at low-dose screening and high-dose recording. The column heading for total radiation dose was set to report a mean dose and/or time for the collective case series.

Procedural Technique

The procedural technique is similar to that previously described [5]. However, as there were differences, particularly for vascular access, and because outcomes or complications may be related to the technique, the procedure is described in detail.

All procedures were all performed by two veterinary cardiologists (lead and assistant) at every centre. Dogs were primarily placed in right lateral recumbency, under general anaesthesia. The right femoral area was clipped and aseptically prepared for surgery before transfer to a radiolucent table designed for fluoroscopy. The left hind leg was positioned to expose the right femoral area and the right hind leg was tied slightly caudally to extend the stifle and hip joints. Antibiotics were given one hour prior to surgery; the choice of perioperative antibiotic use was set by individual practice policy.

Transoesophageal echocardiography (TOE) was performed in dogs weighing greater than 10 kg (but dependent upon the individual case) for imaging and measurement of the PDA as well as for additional procedural guidance, similar to that previously described [9,11,12].

Trans-arterial approach for Amplatz Canine Duct Occluder [i] (ACDO).

The right femoral artery was accessed via a surgical cut-down, close to the inguinal region. Two absorbable stay sutures [j] were placed around the isolated femoral artery and a cannula placed using the modified Seldinger technique. While the assistant held these two sutures, proximally and distally, to control any haemorrhage, the lead interventionalist used a 24 G intravenous Seldinger-compatible cannula (which had a funnel-shaped hub) into the arterial lumen. The stylet was then removed. A 0.018" guidewire was then advanced through the lumen of the catheter into the artery and the cannula removed. A 4 French (Fr) or 5 Fr vascular access catheter and dilator [k] (dogs weighing </> five kg respectively) were passed over the wire and into the artery. Once placed, the wire and dilator were removed, and the distal suture [j] ligated to occlude the femoral artery. The vascular access catheter was sutured to the skin to prevent accidental removal during the procedure. In one centre (EDN), for large dogs, a larger vascular access catheter was placed (through which the delivery sheath could be passed). To achieve this a 16 G cannula was inserted into the isolated femoral artery, the stylet removed and then a 0.035" wire advanced into the femoral artery. The cannula was then removed and replaced with a larger 7 Fr vascular access sheath [l].

A 4 Fr or 5 Fr pigtail measurement catheter [m] was passed through the vascular access catheter to the aorta, just dorsal to the PDA. Angiography was performed using a pressure injector [n] (15 mL/sec to a maximum pressure of 750 psi). Approximately 1 mL/kg of iodinated contrast [o] (up to a maximum of 20 mL for dogs that weighed greater than 20 kg) was injected through the pigtail catheter.

A recording of the angiogram was then reviewed and measurements of the PDA were made. To allow for the magnification of the image on the screen, measurements were based on a scale taken from the spacing markers on the pigtail catheter within the aorta. Similar to the echocardiographic measurements, the pulmonary ostium and ampulla diameters were both measured. If the transthoracic echocardiographic, TOE and angiographic measurements differed significantly, then the imaging modality that was considered to be the optimal image by the lead clinician was selected as the most representative of the true diameter.

An ACDO device size was based a waist diameter (Fig 2) being 1.75 to 2.0 times greater than the pulmonary ostium [5], with an additional secondary consideration that the width of the shoulders (Fig 2) of the ACDO was at least 2 mm greater than the internal diameter of the ampulla.

Method of Amplatz Canine Duct Occluder deployment

The ACDO was deployed as previously described [6]. The size of the delivery sheath for large dogs was that recommended by the manufacturer of the ACDO, but for smaller dogs and depending upon the diameter of the femoral artery, a delivery sheath one Fr smaller was frequently used. The ACDO was routinely removed from its loader to check safe attachment (ie. that the ACDO was properly screwed onto

the wire) and in small dogs the ACDO was reloaded into a smaller loader (one Fr size smaller), then flushed with heparinised saline to remove all air bubbles. A haemostatic valve was attached to the delivery sheath [p]. A 145 cm safety J-wire [q] was placed through the vascular access sheath into the aorta and the sheath removed, while the assistant held the stay sutures to control haemorrhage. At one centre (EDN), the sheath was not removed if a 7 Fr vascular sheath had been inserted into the artery and a 5 Fr delivery sheath used to deploy the ACDO. The delivery sheath (4 - 7 Fr) with its dilator [r] was passed over the wire and into the aorta. The guidewire was then advanced through the PDA into the pulmonary artery. On occasions this step required guidance with a curved end-hole catheter [s] inserted into the delivery sheath. The dilator and delivery sheath were then passed over the wire into the pulmonary artery, ensuring neither the wire nor the dilator or sheath passed proximal to the pulmonary valve, to avoid triggering arrhythmias in the right ventricular outflow tract. Once in position, the wire and dilator were removed together leaving the delivery sheath within the pulmonary artery. The ACDO within the loader was then passed through the haemostatic valve, and into the delivery sheath and the loader was retracted. Under fluoroscopic imaging +/- TOE guidance, the ACDO was then advanced and deployed across the ostium of the PDA and within the ampulla [6]. The TOE imaging facilitated correct device placement, helping to ensure the protruded distal disc (Fig 2) was positioned close to the ostium as the body (portion proximal to the waist) of the ACDO was released [9]. The ACDO was held in place for five minutes in all centres except one (EDN) who waited for 10 minutes, prior to release, during which time measurements of the waist and shoulders of the ACDO (Fig 2) to assess the device sizing were made. A small bulging of the distal disc caused by constriction from the ostium on the ACDO was expected and compression

of the shoulders of the ACDO (Fig 2) by the walls of the ampulla were observed. Flow around and through the ACDO was monitored with TOE during the procedure and auscultation under the drape after deployment. Blood pressure and electrocardiographic monitoring were observed for any Branham response and increase in diastolic blood pressure. Failure of any bulge warranted an evaluation for the risk of ACDO under sizing. A gentle 'push and pull' test was performed to ensure the ACDO was sized correctly. If the device dislodged, then the ACDO was removed by careful retraction into, while advancing forward, the delivery sheath, and a larger device was implanted. An angiogram was repeated, by hand injection and prior to release if there was any doubt about sizing or excessive residual flow, otherwise it was performed after detachment from the delivery cable. Prior to unscrewing, the sheath was advanced close to the screw interface in order to protect the ductal and aortic walls from damage caused by the screw end of the wire, as it detaches from the ACDO.

Transvenous approach for Amplatz Vascular Plug 2 [t]

An Amplatz vascular plug 2 (AVP2) was used in dogs in which the size of the delivery sheath was likely to be too large or difficult for an arterial approach. A transvenous approach via a surgical cutdown was by the femoral vein (dogs > 2.5 kg) or the left jugular vein (dogs < 2.5 kg). Otherwise, vascular access was similar to that described above.

Retrograde catheterisation of the PDA was performed using a curved end-hole catheter [s] and guidewire [u]. A 145 cm safety J-wire [q] was placed through the end-hole catheter into the pulmonary artery. Once in the location of the PDA, the J-wire was

exchanged for a soft tipped 0.035” straight wire [u]. This was used for retrograde catheterisation of the PDA, passing the wire into the aorta, followed by the catheter. Once in aorta, the end-hole catheter was exchanged for a multi-hole multi-purpose angiographic catheter [v] in order to perform angiography, with the side-holes partially inside the ampulla, but the tip of the catheter in the aorta.

Angiography and measurements were performed and described as above.

Method Amplatzer Vascular Plug deployment

The procedural method of deployment of the AVP2 was similar to that described for Amplatzer vascular plugs and Amplatzer duct occluders [7,13]. The selected size of AVP2 device was based on 1.3 to 1.5 times greater than the diameter of the ampulla. All AVP2s < 8 mm in diameter were delivered via a 4 Fr sheath [r]. The AVP2 was routinely removed from its loader to ensure safe attachment then reloaded and flushed with heparinised saline to remove air bubbles. A haemostatic valve [p] was attached to the delivery sheath or catheter. The multi-hole catheter was removed, leaving the wire in place. The delivery sheath with its dilator was passed over the wire. Once in place, the wire and dilator were removed together leaving the delivery sheath within the aorta. The AVP2, within its loader, was passed through the haemostatic valve, and into the delivery sheath by advancing the delivery wire, before retracting the loader free of the haemostatic valve. The AVP2 was then advanced under fluoroscopic imaging. The distal and middle discs were deployed and gently retracted to fill the ampulla, before the proximal disc was deployed across the ostium. The AVP2 was held in place for five minutes in all dogs prior to release, during which time the body of the AVP2 was measured to assess the device sizing.

Prior to unscrewing the delivery wire, as with the ACDO, the sheath was advanced close to the screw interface in order to protect the pulmonary arterial wall from damage caused by the sharp end of the screw of the mandrill.

Surgical Closure

For both ACDO and AVP2 methods, the access vessel was ligated proximal and distal to the arteriotomy/venotomy site using the preplaced absorbable stay sutures [j]. The subcutaneous fat was closed over these sutures and vessel with absorbable sutures and the skin closed routinely.

Post intervention examination

Physical and echocardiographic examinations were repeated to assess procedure outcome. Echocardiography was performed within 24 hours of the procedure.

The patient was usually discharged the day after the procedure unless it had been in advanced CHF. Sutures were removed by the primary veterinarian after 10 days. Follow-up echocardiography was performed at one to three months at the referral centre or by the referring veterinary cardiologist if the case was a tertiary referral. Additional examinations were performed according to degree of cardiac compromise at initial presentation, owner finances and willingness to travel.

Statistical Methods

Statistical analyses were performed using PAST 4 software [14]. Data were examined visually and formally for normality. Continuous data are expressed as median and interquartile range (IQR), and categorical data as counts and percentages.

The relationship between discharge outcome and medium-term outcome and body weight and age was examined with a Spearman Rank Sum correlation.

To compare groups, an independent samples *t*-test was used for continuous data and chi-squared or Fisher's Exact tests for categorical data. Formal statistical comparisons were made only where raw data were available, and where few cases are reported in both groups only summaries are provided. Statistical significance was set at 0.05.

Results

A total of 339 dogs (Fig. 3) were included in this clinical audit (WLS = 219, HVT = 50, EDN = 38, CPH = 19, OSL = 13). An ACDO was used in 310 dogs and AVP2 was used in 23 dogs (WLS = 12, HVT = 9, CPH = 2). Additionally there were six dogs in which a device was not successfully deployed.

There were 54 crossbreeds, which were primarily first crosses with poodle breeds (cavapoo, Cockerpoo, Labradoodle). Sixty-two pure breeds were represented, of which the most common were Cocker spaniel (n = 31), German shepherd dog (n = 19), Border collie (n = 18), cavalier King Charles spaniel (n = 16), Labrador retriever (n = 12) and English Springer spaniel (n = 11). The median age was eight months (IQR four months to 20 months). There were 57 (16.8%) dogs under four months of age and 81 (23.9%) over two years of age. The median body weight (Fig. 4) was 7.9

kg (IQR 4.9 to 24 kg, range 1.5 to 58.4 kg). There were 19 dogs in the weight range 1.5 to 2.9 kg, of which 12 (63%) received an AVP2. A total of 55 dogs (16.2%) were under 3.9 kg. There were 15 dogs over 30 kg (4.4%).

The smallest dog that received an ACDO was a 2.1 kg, 2.4 month-old Border terrier and the smallest with an AVP2 was a 1.5 kg, four month-old Chihuahua. The largest dog that received an ACDO was a 58.4 kg, 21 month-old Newfoundland, and the largest with an AVP2 was an 11.7 kg, 55 month-old cavalier King Charles spaniel.

The criteria for a successful discharge outcome were met in 325 (95.9%) of cases (Fig. 3). In 10 (3.2%) of the ACDO cases a first attempt had been made with a device that pushed/pulled through, or did not have any bulging of the distal disc, and was replaced by a larger device.

A total of 14 cases (4.1%) were recorded as not having a successful discharge outcome, of which 13 (3.8%) were recorded as also having a procedural complication (Table 1); the single case that was not recorded as a procedural complication was in advanced CHF and had an unexplained sudden death 16 hours post-procedure. The procedure-related mortality was 0.6% (two cases): one dog had a dissection of the ductal or pulmonary arterial wall and died during surgery and one dog developed severe bradycardia following closure during intervention, then died three days later. Six dogs (Table 1) were not closed interventionally due to procedural complications. Five dogs were intended for ACDO placement and one for an AVP2 placement. In one of the five dogs, a femoral arterial approach was made for an intended ACDO placement, but that was unsuccessful, then during the same procedure, a jugular approach was made for an intended AVP2 placement, but that was also unsuccessful. Two of the six dogs, were recorded as having subsequent

successful surgical ligation of their PDA. Five cases had interventional closure but also complications (Table 1). Three of these developed hind limb lameness, in the limb used for access, immediately after the procedure. All dogs were Cocker spaniels (two females, one male), unrelated and from the same centre (WLS). Neurological examination by a board-certified neurologist ruled out iatrogenic femoral nerve damage in all dogs. One of these dogs had ultrasound and CT-angiography of the affected limb, revealing oedema and ischemia in multiple thigh muscles (possibly due to microthrombi) and a thrombus in the right popliteal vein. Symptomatic treatment with analgesia (three of three dogs) and clopidogrel (two of three dogs) was started and complete resolution of the clinical signs occurred within 24 hours in one dog, four days in another dog and two months in the final dog.

For the medium-term follow-up, seven dogs were excluded either because they died or the procedure was unsuccessful, these dogs had all been recorded as having a failure of successful discharge outcome. A further 149 cases (43.9%) were either lost to follow-up or had not yet had a follow-up within the time period. Of the remaining 169 cases in which follow-up was available, 157 (92.9%) had a successful medium-term outcome (Fig. 3, Table 2). Of the 12 dogs without a successful medium-term outcome, 10 had pre-existing complications, of which eight were receiving medications for CHF and two had significant pulmonary arterial hypertension. Another two dogs suffered an unexplained sudden death, one at 15 days and the other at three months post-closure. In three of the dogs that initially continued on medications for CHF, the diuretics and other CHF treatment were stopped, remaining only on pimobendan long-term.

We examined the relationship of discharge outcome and medium-term outcome with age and bodyweight. We found no significant relationships ($P > 0.05$, data not shown).

The total radiation exposure dose was recorded in 282 cases (out of 339 dogs, 83.2%). The median radiation dose was 15.6 milliGray (mGy) (IQR 9.7 to 21.3 mGy, range 1.1 to 89.2 mGy). The exposure time was recorded in 210 cases with a median of 4.41 minutes (IQR 3.2 to 6.8 mGy, range 1.5 to 19.5 mGy). For the cases in which an ACDO was used, the median total radiation dose was 15.2 milliGray (IQR 9.6 to 21.2 mGy, range 1.1 to 89.2 mGy) and median exposure time was 4.3 minutes (IQR 3.1 to 6.2 mGy, range 1.5 to 19.5 mGy); for the AVP2 cases the mean total radiation dose was 20.3 milliGray (IQR 16.8 to 23.9 mGy, range 9.1 to 50.0 mGy) and median exposure time was 8.1 (IQR 5.0 to 10.2 mGy, range 2.5 to 13.5 mGy) minutes. The AVP2 cases took significantly longer with a significantly greater radiation dose ($P = 0.009$).

Discussion

The study demonstrates that a clinical audit is achievable on a real-time and prospective basis in veterinary centres that perform cardiac interventional procedures. Centres can use this auditing process to monitor their outcomes and complications year to year. Any deficiencies in outcomes should be identifiable and addressed by adjusting processes, techniques or training methods in order to raise the standard and drive forward continuous improvement. The findings from our clinical audit may help to provide a benchmark by which others can compare their outcomes and, importantly, allow the profession to raise the standard of care for

patients and their owners. This is similar to the mission of National Institute of Cardiovascular Outcomes Research (NICOR) (https://www.nicor.org.uk/about-nicor/), which is to provide accurate data on cardiovascular outcomes for the public, healthcare providers and the medical profession in order to improve the quality of care and outcomes for patients [4]. Our clinical audit provided outcome measures, identified complications and highlighted areas for improvement for the future.

The successful discharge outcome in this audit was high and is almost identical to that previously reported [15] in a larger population of dogs which included dogs undergoing surgical ligation. Our data are also comparable to those for the interventional closure of PDAs in 1762 children and adults, even though the NICOR clinical audit reports a superior survival at 30 days of > 99.9% (https://www.nicor.org.uk/congenital-heart-disease-in-children-and-adults-congenital-audit/). Greater success rates in a patient population five times larger than ours may reflect the greater experience in interventional cardiology within the field of human medicine but, importantly, may also be a consequence of optimised techniques, and superior training, protocols and post-operative management. The value of the auditing process will come from identifying the procedural differences between human and veterinary interventions, in order to inform on which modifications should be introduced within the veterinary field and then re-auditing to see if outcomes are improved.

Similarly, the complication rate for this clinical audit of 3.8% compares favourably to those previously reported for ACDOs in dogs of up to 3% [16], especially since our patient population was larger and data were collected from multiple centres. By contrast, though, the complication rate for human PDA device closure in a three-year clinical audit was < 0.01%. This included complications up to 30 days post closure

(https://www.nicor.org.uk/congenital-heart-disease-in-children-and-adults-congenital-audit/). Our procedure-related mortality (0.6%) was one third that reported for surgical closure in dogs (1.8) [17] and one quarter of the rate reported previously for catheter-based PDA closure (2.6%) [15], though that also included the use of embolisation coils. Clearly, advances have been made in reducing adverse outcomes, but, compared to the complication rate in people, there are considerable improvements to be made in interventional closure of canine PDA.

Complications were observed with both ACDOs and AVP2s. Five of the ACDO cases and in one AVP2 case there were complications that led to failure to deploy the device. As part of the auditing process, it was important to recognise and quantify the separate stages of PDA closure that can lead to complications. This allows centres to identify specific problematic stages of PDA closure, and focus remedial efforts on them, whether they relate to vascular access, deployment of the device or congestive status of the patient.

An example of the usefulness of this approach comes from identification of lameness as the source of nearly a quarter of the procedural complications. In all of the affected dogs, the course of the lameness along with the absence of femoral nerve injury were consistent with limb ischaemia, and in one dog, venous thrombosis was confirmed. As far as the authors are aware, this has never been reported in dogs. In people, deep vein thrombosis is a rare complication (0.05 - 2.4%) of cardiac catheterisation and is most likely to happen if manual compression of the puncture site occurs, or if concurrent venous puncture is performed [18–21]. Indeed, in infants following venous access, the rate of deep vein thrombosis increases to approximately 15.5% [21]. In all our affected dogs, venipuncture was not performed

but our audit raises the possibility that Cocker spaniels may have a higher risk of venous thrombosis. A much larger number of affected dogs and a detailed analysis of the extent to which Cocker spaniels are represented within the referral centre populations would be required in order for a breed predisposition to be confirmed, or to justify a more aggressive anti-thrombotic policy in these dogs. However, by identifying a possible (albeit unproven) breed disposition, our clinical audit allows interventionalists to instigate minor modifications now that do not increase operating time or expense, such as taking particular care not to inadvertently compress the femoral vein in Cocker spaniels and then test the effect of this modification in a future audit.

Alternatively, some aspects of procedural protocol that are already in place may consume more operating time but remain justifiable following audit. For example, we did not identify any haemorrhagic complications from the surgical cut-down approaches to the femoral artery or jugular vein, or from the use of absorbable sutures for vessel ligation.

Despite the prospective nature of the auditing process, medium-term follow-up proved difficult with nearly half of all dogs lost to follow-up. Although this is not an uncommon feature of clinical trials, adequate numbers of dogs are usually recruited in trials, based on well-defined endpoints and *a priori* power analysis that take dropout rates into account [22]. Auditing is uncontrolled, and monitors data from all dogs undergoing a recognised intervention. Where dogs regain full health and return to normal function, many owners may not see the need for cardiac re-assessment and follow-up. Use of a software system as a standard centre protocol to generate automated requests to consenting owners for feedback might improve this follow-up process.

Despite the limitations to numbers, our audit demonstrates that interventional PDA closure is safe and offers a very good medium-term outcome, especially in dogs that do not have pre-existing CHF or pulmonary arterial hypertension. Sudden death was uncommon, with most medium- and long-term deaths attributable to refractory CHF. Three dogs had unexplained sudden death at two days, five days and three months. There is little information regarding sudden death in the veterinary literature, with most medium and long term deaths attributable to refractory CHF. One case of cardiac arrest is reported immediately postoperatively after ACDO placement [15]. Several major complications of transcatheter PDA closure are reported in the human literature [23], which could result in acute deterioration in the short to medium-term. One recent human case report describes a late aortic dissection adjacent to the Amplatz Duct Occluder device [24].

An important feature of auditing is that it can also monitor the impact of achieving clinical outputs on the clinicians themselves. This is relevant to health and safety in the workplace but also has ramifications for patient safety too. In our audit, we recorded radiation exposure times. All the centres in this audit use pulsed rather continuous fluoroscopy, which can reduce the total radiography dose by as much as 80% [25], especially during prolonged procedures. However, we found that auditing radiation exposure also proved a useful training aid and acted as a reminder of the radiation risk. There was a broad range of exposure times across centres that likely reflected the broad range of complexities encountered and operator experience during interventional PDA closures, and which not only mirrors previously published exposure times for PDA closure in dogs [6] but also those in children [26]. Thus, our audit strongly suggests that there are limitations to fluoroscopic-guidance and supports the use of additional imaging modalities such as TOE, already employed by

some of the centres in this audit, to help reduce radiation exposure, particularly in complex cases.

Another key difference by performing a clinical audit over publishing a clinical trial or case series, is its continuous process, and evolving nature that allows changes in approach, equipment and experience in single or multiple centres to be compared with baseline levels of performance. If outcomes are favourable, these then establish levels of performance for future comparisons. A good example of this from our audit is the incorporation of the AVP2 device to close PDA in very small dogs that, at other centres, may have instead undergone surgical ligation of their PDA. For new techniques to become established, it is important that they compare favourably with those already in place. Here, we provide success and complication rates that can be compared with published surgical complication rates in similar sizes of dogs [27] and larger dogs undergoing surgical closure by ACDO [15]. In retrospective studies it is possible for there to be under-reporting if some cases get 'forgotten' when a procedure is aborted prior to commencement so that the procedure is not recorded in the clinical records; in this clinical audit patient details were entered prior to commencement.

We were unable to identify an association between outcome and body weight or age. This is a novel finding and somewhat surprising but nonetheless important because audits are more valuable when they represent the entire patient population, and the bodyweight range in our audit was approximately double that previously published [15]. Prior to audit, the authors considered technical aspects, such as vascular access and device sizing in very small dogs, or anaesthetic risks in very young dogs as factors that contribute to adverse outcomes. Our complication rate was low and this may have limited our ability to detect a difference if one does exist.

Nevertheless, it is encouraging that even when performed in very small (under 3 kg) or very young (under four months old) dogs, interventional PDA occlusion does not appear to involve an increased risk of short or medium-term complications. Our finding that one quarter of our patient population was older than two years of age is consistent with a previous report [28]. This should be of significant concern to the veterinary community, since, in general, the characteristic loud, palpable, continuous left heart base murmur along with bounding pulses is present in most cases from a very young age and almost pathognomonic for the condition. This could be addressed through appropriate training at undergraduate and primary care level. Future auditing would determine whether or not remedial efforts had been successful.

An important step when performing clinical audit is critical reflection on information gained during analysis, which is part of the re-audit cycle. Following our initial examination of the data, we wanted to look in more detail at specific risk factors that experience or clinical research have found to relate to outcomes in PDA, however, our initial audit design did not allow for this. Following discussion, we have decided to update our audit data collection spreadsheet to include pre-operative “high-risk, low risk” cases, based on pre-defined risk factors such as presence of CHF, pulmonary arterial hypertension or significant arrhythmia necessitating antiarrhythmic therapy. Future audits will allow us to examine these risk factors in more detail and evaluate whether they do indeed influence outcome. The database also need to be modified to identify cases, that were not successful due to complications, which device had been planned and by which route vascular access was attempted. It might also be useful to record the total procedural time.

Conclusions

In conclusion, this clinical audit demonstrated that the process of performing an audit is achievable in veterinary cardiac interventions. The successful discharge outcome rate for interventional PDA closure of 96.9% falls short of the standards set in human medicine (> 99.9%) and thus there is room for improvement. Nevertheless, we were able to establish a benchmark for other centres to consider for their own clinical audit. The numbers in this audit were too small to provide individual audit by centre or by the individual, but in due course these may also become feasible. We encourage all centres performing similar procedures to undertake their own clinical audit, which would help to identify areas for improvement and ensure standards are met in training new colleagues in these procedures. Finally, the implementation of clinical audit could be applied to a wide range of other clinical procedures and should be considered in other aspects of veterinary medicine.

Conflicts of Interest Statement

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

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Footnotes

h Excel Microsoft Corporation, Richmond, WA.

i Amplatz Canine Ductal Occluder, Infiniti Medical™, Menlo Park CA, USA.

j Monocryl, Ethicon, Somerville, NJ 08876, USA.

k Performer Introducer access set, Cook Medical, Bloomington IN, USA.

l Introducer II Radiofocus, 7 F, Terumo, Liverpool, UK

m Occlu-Marker pigtail measurement catheter, PFM medical, Köln, Germany

n Angiomat 6000 contrast injector, Liebel-Flarsheim, Mansfield, USA

o Niopam 300 solution, Bracco UK Ltd, High Wycombe, Buckinghamshire, UK

p vascular sheath Check-Flo® Introducer Set, Cook Medical, Bloomington IN, USA.

q 145 cm safety J-wire, Fixed-Core Wire Guide, Cook Medical, Bloomington IN, USA.

r Flexor Ansel Guiding Sheath, Cook Medical, Bloomington IN, USA.

s Torcan NB Advantage Catheter, Cook Medical, Bloomington IN, USA.

t Amplatz II Plug, AGA Medical Corporation, Plymouth MN, USA.

u 150 cm floppy tipped Wholey Guidewire, Medtronic, Watford England

- v 5 F MPA multihole Torcon NB Advantage catheter, Cook Medical, Bloomington IN, USA.

Figure legends

Figure 1

Example of the column headings for the clinical audit in the Microsoft Excel spreadsheet [h]. Note that the percentage will change with each new entry.

Figure 2

Schematic diagram of the Amplatz Canine Duct Occluder clarifying the terminology used for the ‘distal disc’ and the ‘proximal portion’, as well and the two key measurements for the ‘waist’ and ‘shoulders’.

Figure 3

Flow chart showing the number of cases, discharge outcome and complications in 339 dogs with Patent Ductus Arteriosus

Figure 4

Relationship between weight of patient and size of device. The Amplatzer Vascular Plug 2 were only used for dogs less than 12 kg.

ACDO: Amplatz canine duct occluder, AVP2: Amplatzer vascular plug 2

Figure 1

Example of the column headings for the clinical audit in the Microsoft Excel spreadsheet [h]. Note that the percentage will change with each new entry.

						Average Total Radiation DOSE	Average total screening TIME (minutes)	Successful Discharge Outcome	Successful Medium Term Outcome	Procedure Complication Rate	
Number of Cases						17.5	5.5	95.9%	92.9%	4.1%	
Date	Name	Breed	Body weight (kg)	Age (months)	Vet lead	Total radiation (mGy)	Radiation time (minutes)	Discharge outcome	Medium term outcome	Complications	Comments:
Insert New Case At Bottom											
02-Jan-16	Pet identification	Crossbreed	5.8	6.8	MM	6.8	3.1	1	1	0	
23-Feb-20	Pet identification	Border collie	18	4.5	MM	4.5	2.5	1	1	0	

Figure 2

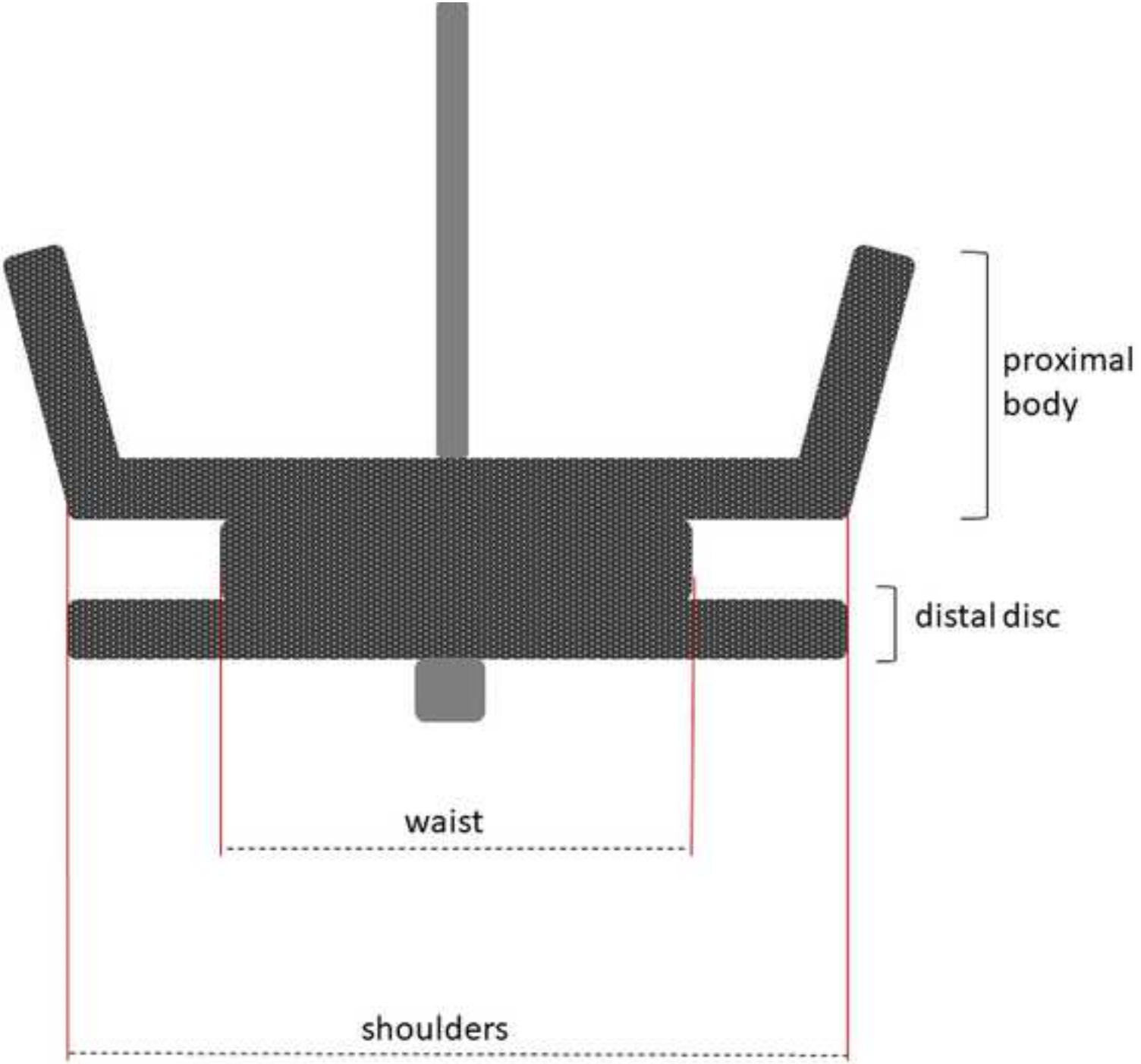

Figure 3

Flow chart showing the number of cases, discharge outcome and complications in 339 dogs with Patent Ductus Arteriosus

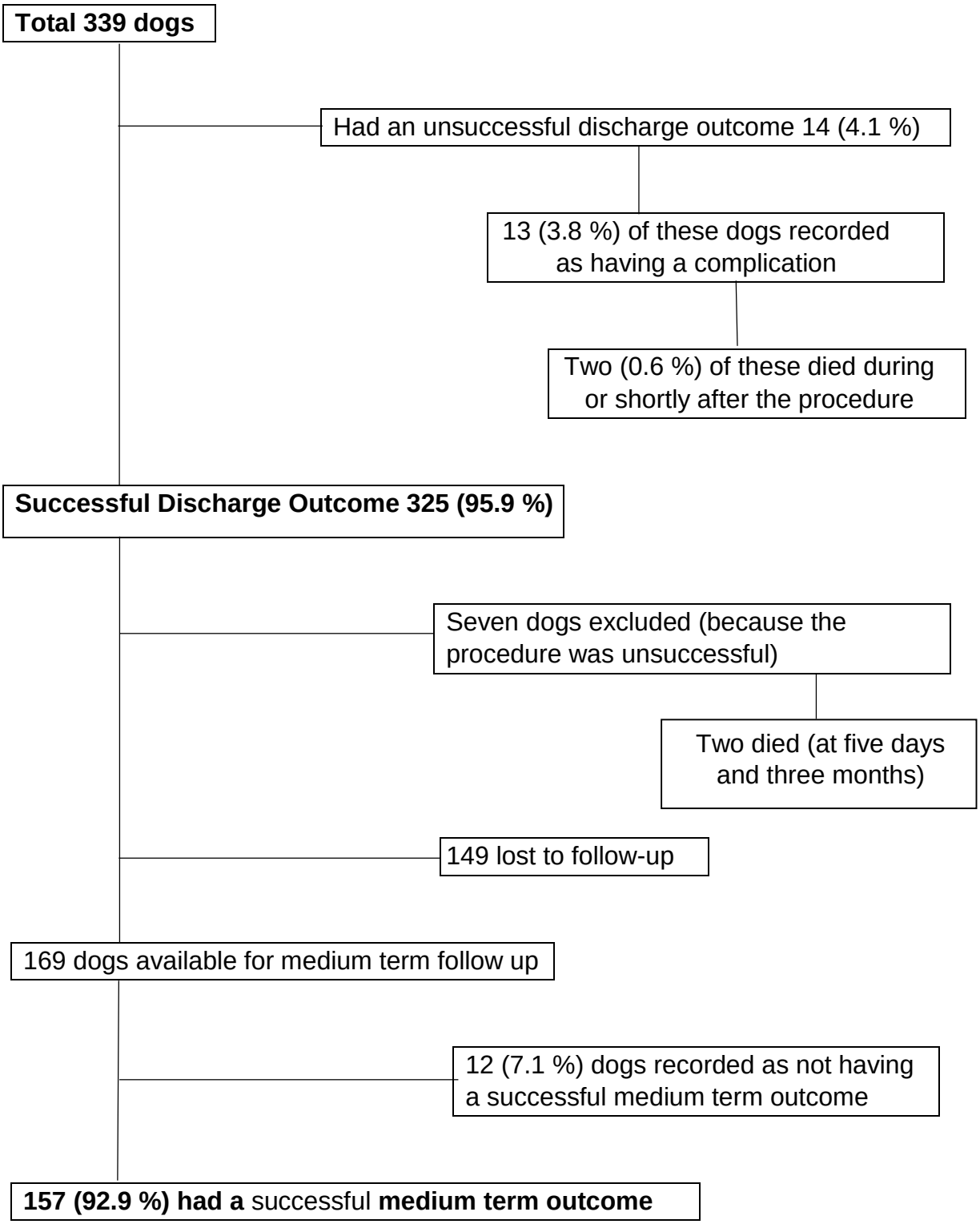

Figure 4. Relationship between weight of patient and size of device. The Amplatzer Vascular Plug 2 were only used for dogs less than 12 kg.

ACDO: Amplatz canine duct occluder, AVP2: Amplatzer vascular plug 2

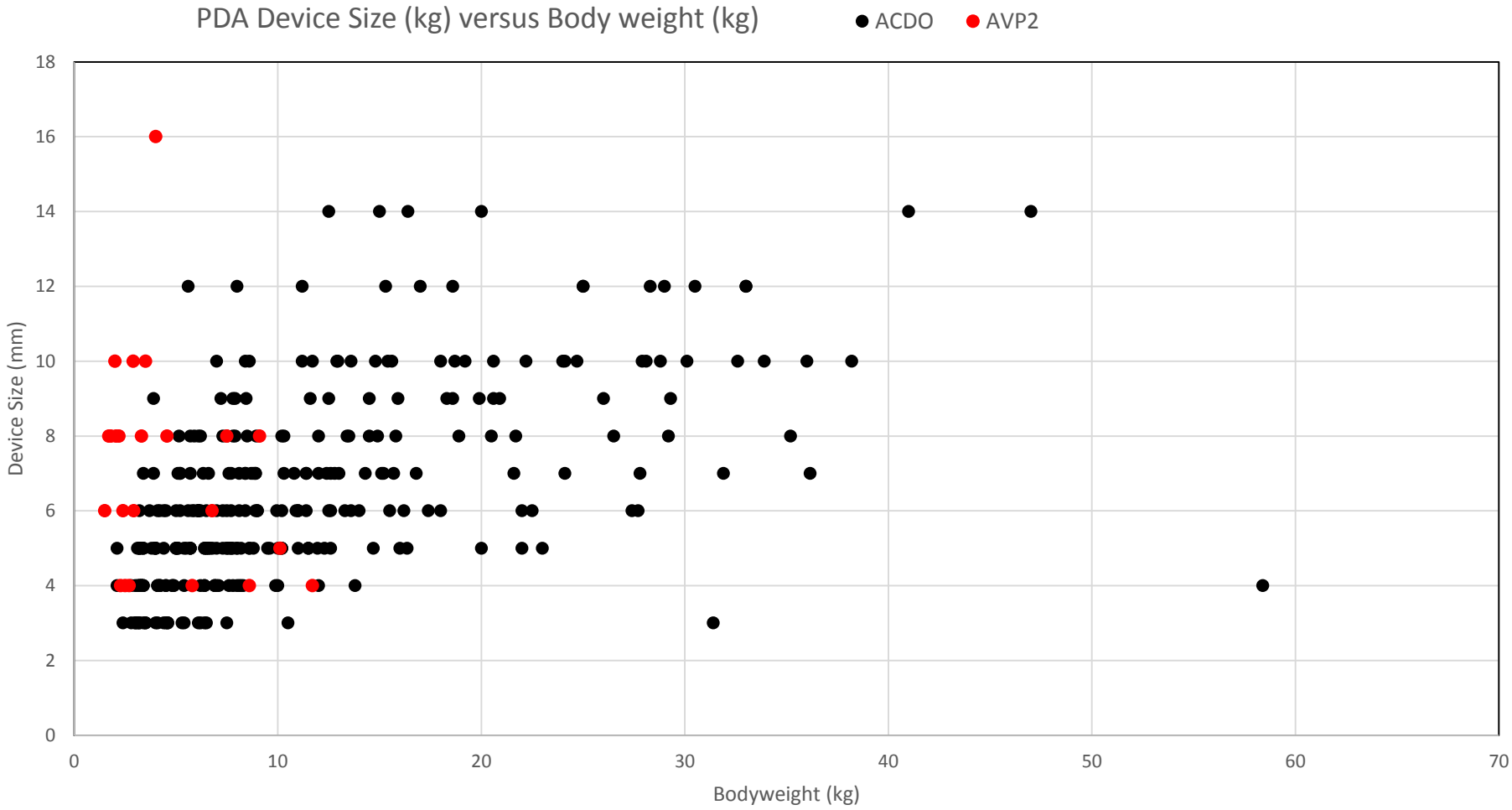

Table 1. Complications encountered and the notes made to explain the nature of the complications. All these 13 dogs were recorded as having both an unsuccessful 'discharge outcome' and a 'complication'. An entry of a – indicates no-recording.

ACDO: Amplatz Canine Duct Occluder, AVP2: Amplatzer Vascular Plug 2, CHF: Congestive heart failure, PDA: Patent ductus arteriosus

Breed	Weight (kgs)	Age (mths)	Total radiation (mGy)	Radiation time (mins)	Intended device	Device Size (mm)	Notes
Chihuahua	3.0	12	12.2	12.1	AVP2	-	Attempt to catheterise the right ventricle was made but progressive bradycardia and hypotension. Procedure aborted.
Chihuahua	3.3	36	-	7.50	ACDO	4	Dissection of the ductal-pulmonary arterial wall during catheterisation, dog died shortly afterwards
Cocker Spaniel	5.5	2.2	-	-	ACDO	-	Duct was disproportionately large requiring a 6 F delivery sheath, artery tore during attempts to insert sheath; dog was closed surgically.

Cocker Spaniel	6.1	3	22.8	5.2	ACDO	8	Lameness of right hind limb post interventional closure. Received physiotherapy.
Cocker Spaniel	10.3	16	24.6	6	ACDO	8	Lameness of right hind limb post interventional closure, possible thromboembolism.
Cocker Spaniel	12.8	3	9.4	3	ACDO	7	Lameness of right hind limb post interventional closure.
Crossbreed	3.2	9	75.5	23	ACDO	5	Duct was short, in unusual position and angle, ACDO dislodged 30 minutes later. PDA reversal occurred 1 week later
Crossbreed	17.0	156	23.7	4.3	ACDO	12	ACDO embolised in recovery; dog was already in CHF requiring medications
Dobermann Pinscher	29.2	8	89.2	14.4	ACDO	-	Dislodgement of device due to unusual shape of PDA, had surgical ligation
German Shepherd Dog	15.6	7	15.6	5.4	ACDO	10	Developed device infection four weeks post-op

Irish Setter	5.6	31	37.0	3.4	ACDO	12	Bradycardia post release (24 beats per minute). Died three days later.
Pomeranian	2.4	9	26.7	19. 5	ACDO, then AVP2	-	Attempts to catheterise the femoral artery failed (for an intended ACDO placement), the procedure was switched to a jugular approach for an intended AVP2 placement, but during right ventricular catheterisation a progressive bradycardia and hypotension developed and the procedure was aborted.
Welsh Corgi	3.9	3	8.3	-	ACDO	9	Intraabdominal haemorrhage due to distal aorta perforation, dog lived and duct was occluded

Table 2. Patient description as well as device and type of complications in the 12 dogs recorded as not have a good 'medium term outcome'.

ACDO: Amplatz canine duct occluder, AVP2, Amplatzer vascular plug 2, CHF: Congestive heart failure, CKCS: Cavalier King Charles Spaniel, GSD: German shepherd, PAH: Pulmonary Arterial Hypertension

Breed	Weight (kgs)	Age (mths)	ACDO (mm)	AVP2 (mm)	Comments
Border Collie	16.4	10	14		Sudden death three months post-procedure
Chihuahua	5.1	2	5		Severe PAH, appeared to be improved with sildenafil prior to intervention, producing a continuous but low flow left-to-right flow of 2.4 m/s. However remained in right CHF afterwards
CKCS	7.5	32	5		Marked cardiomegaly with CHF continued to require CHF medications
Cockerpoo	6.6	3	5		Continuing CHF and impaired systolic dysfunction, requiring medications
Cross breed	8.6	29	10		Had PAH prior to surgery, reduced with sildenafil producing a continuous but low flow left-to-right flow of 2.1 m/s, and then closed. Continued with right sided CHF requiring medications
Cross Breed	11.2	24	12		Continuing CHF with cardiomegaly & ventricular arrhythmias, requiring medications
Cross Breed	3.5	3		10	CHF and Mitral Dysplasia, remained on pimobendan

GSD	32.6	72	10		Mild cardiomegaly and continued on pimobendan
Labrador	7.0	8	10		Continued in CHF despite closure and requiring medications
Spanish Waterdog	4.5	2	6		Left ventricle remained dilated with poor systolic function and remained on pimobendan
Standard Poodle	8.4	4	10		CHF and cardiomegaly remained on medications
Siberian husky	20.0	5	14		Sudden death five days post-procedure

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The following information is required for submission:

Author contribution

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Please specify the contribution of **each author** to the paper, e.g. study concept or design, data collection, data analysis or interpretation, writing the paper, others, who have contributed in other ways, should be listed as contributors.

Mike Martin – all aspects from study design to writing

Brigite Pedro – study design, data collection, critical revision & writing, final approval

Dave Dickson – study design, data collection, critical revision & writing, final approval

Joao Neves – data collection, critical revision & writing, final approval

Jo Harris – data collection, critical revision & writing, final approval

Yolanda Martinez Pereira – data collection, critical revision & writing, final approval

Maria Ines Oliveira – data collection, critical revision & writing, final approval

Jakob L Willesen – data collection, critical revision & writing, final approval

Liva Vatne – data collection, critical revision & writing, final approval

Geoff Culshaw – data collection, critical revision & writing, final approval

Chris Linney – study design, data collection, critical revision & writing, final approval

As **Corresponding Author** I hereby confirm that all listed authors in the submission meet these Criteria.

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Please add signature here:

Date 2 March 2022