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ORIGINAL RESEARCH

Study design quality of research on dogs published in peer-reviewed journals

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Abstract

Background: In the past it has been criticised that only a low proportion of well-designed and well-reported studies in some medical specialities is available. The objective of this study was to systematically evaluate the quality of literature about canine medicine published in peer-reviewed journals in relation to six specific veterinary medicine specialities.

Methods: A literature search was conducted and 25 studies per speciality were selected. The quality of the articles (n = 150) published between 2007 and 2019 was evaluated with a validated checklist.

Results: In articles related to all specialities, deficits were found, such as not adequate number of animals in 60.0% of the studies. In 88.0%, information about housing and feeding of the dogs were not specified. In 69.4% of the prospective clinical studies, an ethical approval was reported, and written informed consent of the owners was obtained in 46.2%.

Conclusions: The findings revealed extensive deficits in the design and reporting of studies in canine medicine. The demand for improvement is obvious and should be addressed by authors, reviewers and journal editors in the future. Our results underline that practitioners should critically appraise the quality of literature before implementing information into practice.

KEYWORDS
evidence-based veterinary medicine, literature quality, veterinary specialities

INTRODUCTION

Every year an immense amount of new scientific veterinary information is published. Many authors claim that practitioners should be aware of the latest research findings in order to choose the best examination and treatment options of their patients.[1] According to the evidence-based veterinary medicine (EBVM) manifesto launched by Vet Record, it is necessary to bring the best available evidence into the consultation room so that particular problems can be better handled by the veterinarian and that clients are better informed about the options they are given.[2] The latest scientific information is usually brought to the veterinarian via scientific journals. Most of the research articles go through a peer-review process in order to ensure the high quality and scientific relevance of the studies published.[3]

Nevertheless, it has been claimed that the practitioner has to be able to appraise the evidence and quality[4] because articles in scientific journals may be of low quality and prone to bias.[5,6] Due to the packed curriculum of veterinary studies, however, the ability to appraise the quality of studies is hardly trained in many veterinary schools.[7] This means that many veterinarians may not be sufficiently aware of possible weaknesses within the scientific literature.[8]

In order to help practitioners to appraise published studies, an online resource has been published: https://learn.rcvsknowledge.org/course/view.php?id=2

For the classification of the different types of information, evidence levels were defined[9] and a 'staircase of evidence' was developed.[6] Meta-analyses and randomised controlled trials (RCTs) are the sources of information that have the lowest risk of bias. Well-conducted meta-analyses can help practitioners by providing overall conclusions after statistically summarising the results of different randomised, controlled studies focussing on a specific clinical problem. Sadly, in veterinary medicine, only a few meta-analyses have been published to date.[10] Opposed to that is information belonging to the weakest level of evidence; for example, expert opinions or single case

reports. These sources of knowledge are considered to have a high risk of bias.

Next to the levels of evidence, other aspects need to be taken into account for appraisal of the quality of research papers. These aspects include, for example, the number of experimental animals or samples used, the appropriateness of statistical methods, the handling of missing data and the objectiveness of the discussion.[11] To support a more systematic appraisal literature evaluation, checklists have been published.[12]

Quality deficiencies in veterinary literature have been identified in peer-reviewed veterinary journals in recent years.[13–16] For example, by taking a closer look on the literature on reproduction in dogs, Arlt et al.[17] found that the majority of publications reviewed referred to low evidence levels and did not draw sound conclusions. Simoneit et al.[11] compared the literature on bovine, canine and equine reproduction and confirmed a low quality of many RCTs. Substantive deficits exist likewise in the reporting of publications on bovine and canine trials as well as in bovine and porcine conference proceedings.[18–20]

In the context of the identified quality deficiencies, the question arises if limitations vary between veterinary specialities.

The objective of this project was, therefore, to evaluate the quality of studies on dogs related to six different veterinary medicine specialities: cardiology, internal medicine, neurology, orthopaedics, reproduction and surgery. The quality was assessed with a validated checklist published by Arlt et al.[17]

MATERIAL AND METHODS

A literature search in the databases PubMed (www.pubmed.gov) and CAB Abstracts (www.cabdirect.org/) was conducted on 31 October 2020.

The following search keywords were used: Clinical trial AND dogs AND speciality. For each search procedure *speciality* was replaced by cardiology, internal medicine, neurology, orthopaedics, reproduction and surgery. Terms were connected with the Boolean operator 'AND'. The obtained bibliographic records were transferred into six lists using Endnote (Alphasoft GmbH, Frankfurt am Main, Germany).

The publications found for cardiology were 2981 (PubMed) and 88 (CAB Abstracts), internal medicine 7730 (PubMed) and 906 (CAB Abstracts), neurology 953 (PubMed) and 106 (CAB Abstracts), orthopaedics 523 (PubMed) and 507 (CAB Abstracts), reproduction 6403 (PubMed) and 525 (CAB Abstracts) and for surgery 7698 and (PubMed) 5192 (CAB Abstracts). The search lists were merged together, and duplicates were deleted.

We assigned an individual number to every article. From each list 50 articles were selected with a random number generator (https://rechneronline.de/zufallszahlen/).

Specific inclusion and exclusion criteria for articles were defined before the literature search was conducted. Publications had to be in English or German language and published between and including 2007 and 2019.

Case reports or case series with a number of animals lower than $n < 10$, opinions or clinical experiences and abstracts with less than 500 words were excluded.

Availability of the articles via internet or the veterinary libraries of Berlin, Hannover, Gießen, Leipzig or Munich was necessary for inclusion of the articles into the study. Papers which were not available and could not be obtained via inter-lending were excluded.

Studies or case reports without statistical analysis and studies on other species such as humans, cats or other were excluded. In addition, in vitro studies were not included.

Studies were defined as interventional studies if the researchers applied interventions in a retrospective or prospective manner. The definition of observational studies comprised cross-sectional, cohort or case control studies and case reports (with $n > 10$), in which the investigator did not act upon study participants, but instead observed natural relationships between factors and outcomes.[21]

The number of articles which met the inclusion criteria from the initial randomly selected 50 articles per speciality were 28 for cardiology, 26 for internal medicine, 29 for neurology, 28 for orthopaedics, 30 for reproduction and 27 publications for surgery. For further article selection and analysis of the data, the software SPPS (Version 25.0; SPSS Inc., Munich, Germany) was used. For the second randomisation, SPSS 'Random sample of cases' function was used to obtain the final 25 studies per speciality.

From these final 150 articles, 134 articles were accessed via online databases, nine papers were retrieved in the veterinary library of the University of Berlin and two articles were obtained via inter-lending from other libraries.

The assessment of the articles using the checklist (Appendix 1) was trained in a pretest with 10 articles by three investigators. The results were compared, and the classification was standardised where necessary. Only single assessment results varied among the three investigators, variation was in no case more than one grading point. As repeatability of classification conducted by the three independent investigators was substantial, only one investigator continued with the assessment.

For evaluation of the literature, a slightly modified version of the checklist developed in 2010 by Arlt et al.[17] was used. The checklist assesses the parameters 'material and methodology', 'study design', 'statistics', 'presentation and information content', 'practical applicability' and 'conclusions', whether the data are sufficient to draw sound conclusions.

One modification was that the option of choosing 'neutral' was not available for this study. The answer categories are a scale from 'strongly agree', 'agree' to 'disagree' or 'strongly disagree' or 'not determined'.

Furthermore, the authors agreed on strict assessment patterns: if no information regarding a specific item of the checklist was given in the article, the parameter was set 'disagree'. If information for a

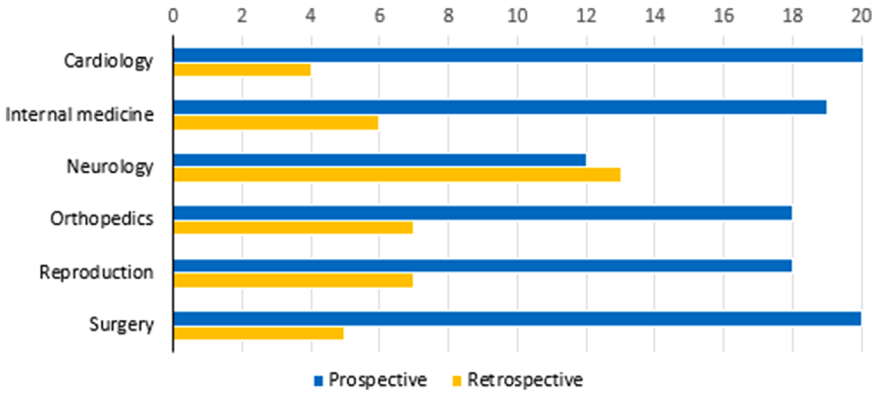

FIGURE 1 Number of articles per veterinary speciality with a prospective versus retrospective approach ($n = 150$)

specific parameter was given partly, for example if age or breed of the dogs was given for some but not all animals, this item was also categorised as 'disagree'. Only if the information of the checklist parameter was given for all dogs used in the study, the answer was set 'agree'.

In addition to the items of the checklist, the ownership of the dogs used for the trials was documented. Every prospective study was checked for information on owners' consent and if an ethics committee approved the study.

Statistical analysis

All statistical analyses were conducted in IBM SPSS for Windows (Version 24.0; SPSS Inc.). Categorical data were presented descriptively as raw numbers and percentages. To identify differences between the specialities, the non-parametric Mann–Whitney *U*-test was used as indicated by the distribution. Statistical significance was set at $p < 0.05$.

RESULTS

General information about the papers

The selected 150 articles were published in 62 different journals, 108 (72.0%) were prospective and 42 (28.0%) were retrospective. Taking a closer look at the specialities, cardiology had the highest proportion of prospective articles ($n = 20$ articles, 80.0%) and neurology the most retrospective studies ($n = 13$ articles, 52.0%, $p < 0.05$) (Figure 1).

Analysing the countries of the affiliation of the authors revealed that 30 different countries were represented in total. The majority of authors ($n = 39$ articles, 26.0%) belonged to institutions in the US, followed by the UK ($n = 17$ articles, 11.3%), Germany, Switzerland and China (each $n = 8$ articles, 5.3%).

Considering the study design, 91 of 150 appraised publications were classified as interventional studies (60.7%) and 59 were observational studies (39.3%, Figure 2). The most interventional studies were found in surgery, with 19 articles. The most observational studies ($n = 15$) were published in the field of neurology ($p < 0.05$).

The results of the evaluation of materials and methodology of the 150 studies revealed that the objective was given for most of the studies (98.6%) (Figure 3a). When it comes to the housing of the animals used in the clinical studies, it was described in 12.0% of the 150 articles (Figure 3b). The housing of the dogs was more often documented for dogs which were not client owned but bred or kept as experimental animals.

When it comes to the specification of the inclusion criteria of the dogs, most authors of articles on internal medicine, neurology and surgery documented them. However, in 11 (44.0%) articles on cardiology and nine (36.0%) on orthopaedics and reproduction, respectively, inclusion criteria were not specified (Figure 3c).

Demographics of the sample population

In 98 (65.3%) articles, the breeds of the dogs used in the study were documented. The proportion of articles including complete breed information was highest in neurology (80.0%), cardiology and surgery (each 76.0%) (Figure 3d).

In 25 (16.6%) out of 150 studies, the age of all dogs was given (Figure 3e). More specifically, in none of the articles on reproduction the age of all enrolled dogs was specified, while the highest proportion of articles including age information was found in studies on surgery ($n = 8$, 32.0%, $p < 0.05$).

Study size of the evaluated literature

The number of the animals used for the study was given in most of the articles of all different specialities. For two studies, one on reproduction and one on orthopaedics, the authors did not specify the number of enrolled animals. The median sample size for all included studies was 31 dogs (Q1: 16; Q3: 64). For the different specialities, the median sample size was mostly homogenous (Table 1).

For 90 (60.0%) of the 150 articles, the number of animals should be considered not adequate (Figure 4a). The sample size was predominantly too small in neurology ('strongly disagree' and 'disagree': 19 studies) and the most adequate in reproduction trials ('strongly agree' and 'agree': 13 studies, $p < 0.05$). A power

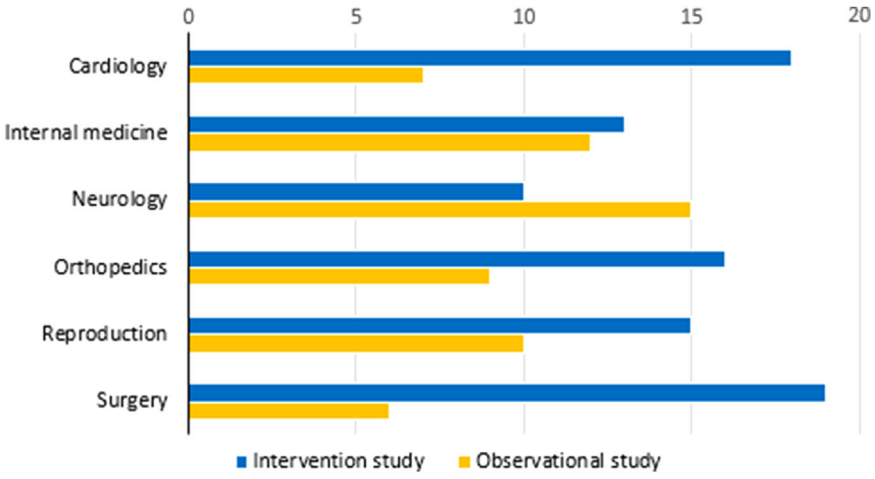

FIGURE 2 Number of articles per veterinary speciality with an interventional versus observational approach ($n = 150$)

TABLE 1 Median sample size and quartile (Q1/Q3) of 25 studies per veterinary speciality (six) and total ($n = 150$)

Speciality	Median sample size	Quartile Q1	Quartile Q3
Cardiology	32	22	207
Internal medicine	31	14	53
Neurology	33	15	56
Orthopaedics	36	19	95
Reproduction	35	18	74
Surgery	25	16	40
Total	31	16	64

calculation in order to determine the sample size of a clinical study was documented for less than 45.0% of the articles.

Statistical analysis

For the adequacy of statistical analysis of the studies three main items were reviewed, which were the description of statistics, the number of animals and information about handling of missing data (Figure 4).

In total, the description of the statistics was adequate and comprehensible in 95.3% of the articles. In cardiology, internal medicine and surgery two articles were identified that did not fulfil the criteria (Figure 4b). Although *p*-values were given, there was no information on applied statistical tests.

When it comes to the handling of missing data, in 48% of the studies potential missing data were described. For the specialities surgery and internal medicine authors of 15 articles each (60.0%) referred to missing data, while for orthopaedics and reproduction this was true in eight articles (each 32.0%, $p < 0.05$) (Figure 4c).

Ethical approval and owners consent

The evaluation of the prospective studies regarding an ethical approval revealed no differences between the specialities. For 71.4% of cardiology studies, 73.7% of internal medicine studies, 75.0% of neurology studies, 77.8% of orthopaedic studies, 62.1% of reproduction studies and for 64% of surgery studies an ethical approval was documented.

The results of the assessment for ownership information and information about informed consent of the owners led to four potential outcomes (Figure 5). Either the dogs were experimental animals owned by the research institutions, the origin of the dogs was not described, an informed consent was given by the owners or informed consent for privately owned dogs was not documented. For research in the field of cardiology in 11 of the articles (44.0%) experimental animals were used. The written consent was best documented in articles on internal medicine with 10 articles (52.6%) and neurology with nine articles (75.0%, $p < 0.05$). There were two articles in surgery and two in reproduction in which the origin of the dogs was not documented.

DISCUSSION

Veterinarians need to apply the best available evidence and inform their clients based on the latest research findings. In that regard, practitioners have to read and appraise the evidence and quality of articles published in scientific journals. The use of invalid or biased information may lead to misleading diagnoses or treatment failures.

Studies which identify limitations of recently published studies may be helpful in terms of pointing out factors which should be focused on when reading scientific articles. In addition, they may help to improve planning and reporting studies.

This project evaluated with the help of an approved but slightly modified checklist the quality of 150 studies belonging to six different veterinary medicine specialities. The six specialities were chosen because of their clinical relevance and relevance in the veterinary curricula. It has to be noted that no international uniform definitions for the specialities exist and that they may overlap considerably. In addition, some authors see the term ‘internal medicine’ as a superordinate

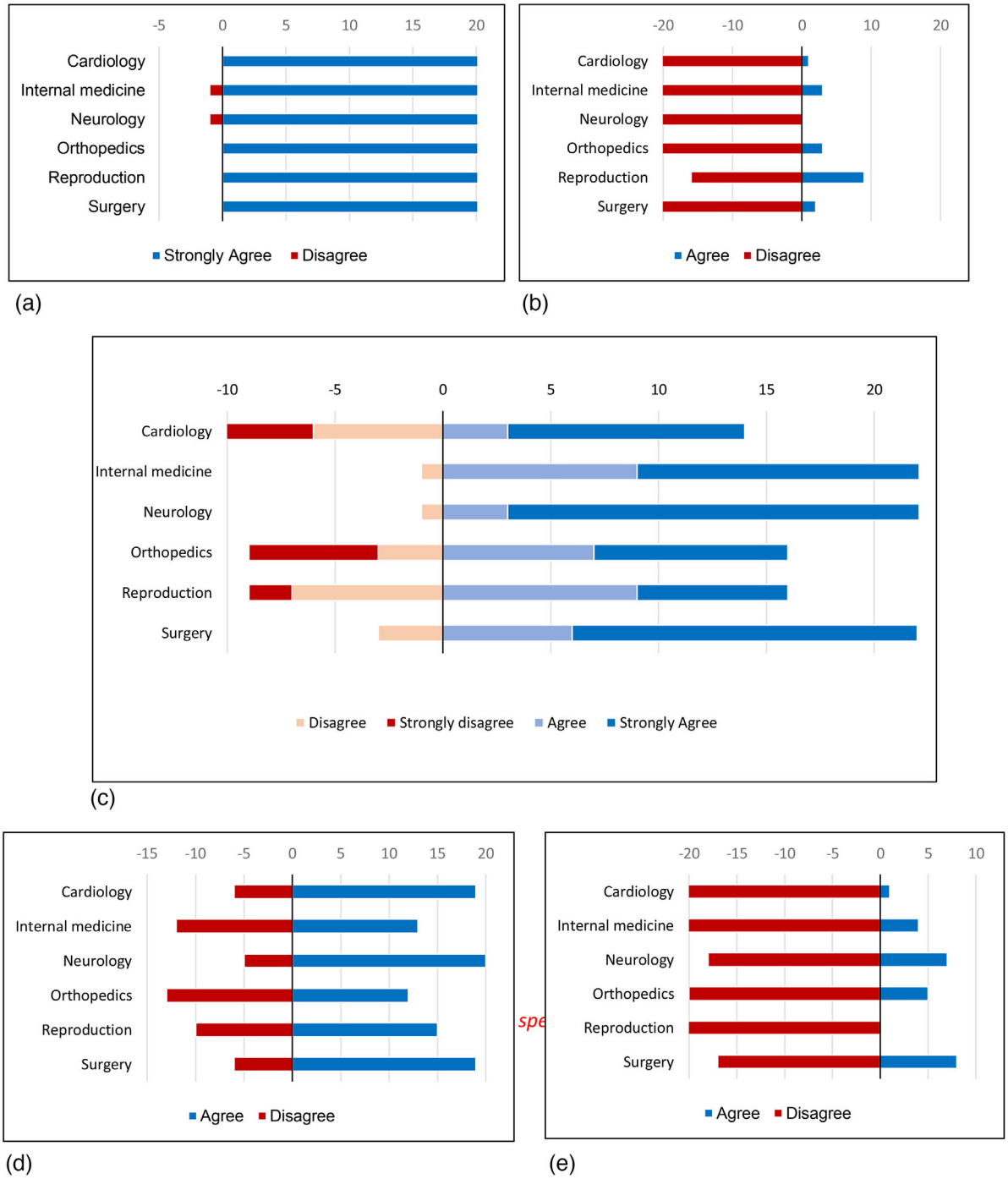

FIGURE 3 Critical appraisal of the material and methodology statements (a–e) of 150 veterinary studies within the six veterinary specialities (each 25 studies) via approved checklist and agree/disagree scale: (a) the objective of the study is presented; (b) housing information about the animals is given; (c) inclusion criteria about the animals is given; (d) breed of the animals is given; (e) the age of the animals is given

and general term, which may encompass fields such as endocrinology, neurology, cardiology, oncology, infectious and immune-mediated diseases.[22] The definition of fields as speciality or sub-speciality and their relevance may depend on the local conditions and can differ therefore considerably. For this project, neurology and cardiology were defined to be separate specialities.

It is noteworthy that most prospective studies were found in surgery and cardiology. This might be due to the better standardisation possibilities of the patients or different research approaches within these specialities. Another hypothesis could be that pharmaceutical companies are more willing to fund prospective trials in specific specialities. In comparison with human medicine, veterinary medicine has been historically allotted less funding[23] but it should be assessed in future research projects if funding really varies between veterinary specialities.

The high proportion of retrospective neurology studies might be due to the more reviewing character of the best-practice treatment for known diseases

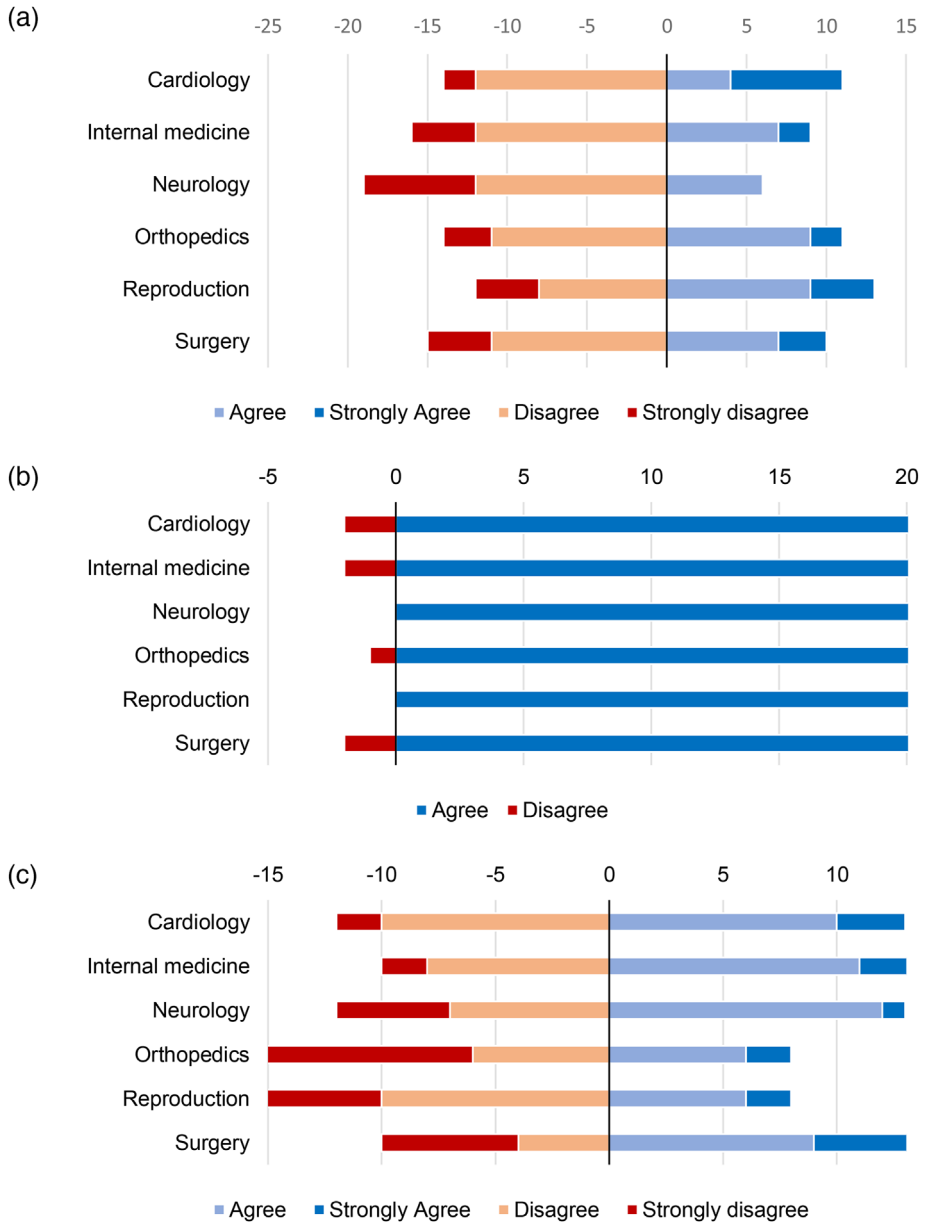

FIGURE 4 Outcome of statistical review of six veterinary specialities (each 25 studies) via approved checklist with an agree/disagree scale ($n = 150$): (a) number of animals adequate; (b) description of statistics is adequate and comprehensible; (c) handling of missing data is adequate and comprehensible

like epilepsy or the difficulty of having enough animals or funding for prospective studies. These circumstances are also reflected when it comes to the study type. The most interventional studies can be found in surgery, the lowest number in neurology. This seems to indicate that surgery trials may be more designed to assess new treatment protocols or procedures rather than evaluating established methods. According to our results, most studies were prospective. In the context of an appeal by Kastelic,[24] who described a shortage of prospective randomised, controlled studies in veterinary medicine in 2006, it seems that the situation has improved.

It is remarkable that for nearly 90% of the studies no details about housing and husbandry of the dogs were given. This is in accordance with earlier findings after assessing literature on canine reproduction.[17] This was especially the case for privately owned dogs. It can be hypothesised that housing and feeding was so heterogeneous that a detailed description was regarded not possible or not reasonable. However, depending on the research question it might be of interest if dogs, for example, are kept in kennels or in the household and if they were fed a conventional diet or raw meat. For experimental animals, housing and feeding were usually specified in detail. Articles on reproduction seem to stand out with nine articles mentioning the housing.

The number of enrolled dogs was given in most articles, even for retrospective studies with high numbers of animals. When it comes to the specification of inclusion criteria, most deficiencies were found in

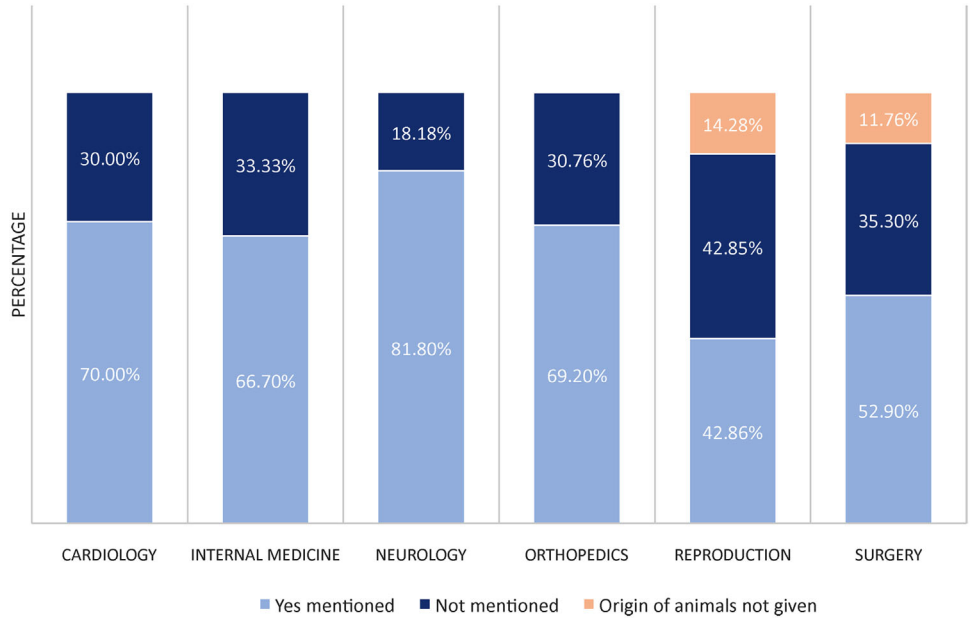

FIGURE 5 Percentage of articles with client owned dogs per speciality that mentioned the written informed consent of owners in prospective studies ($n = 80$)

cardiology and orthopaedics. Clear criteria and definitions of diseases should always be given in scientific articles. In many trials, the presence of specific diseases or conditions was used as an inclusion criterion. For readers, definitions of inclusion and exclusion criteria are essential to decide if a present case is comparable to the study population or not.

The breeds of the dogs were given in most articles, although this information was missing in a higher proportion in articles on internal medicine and orthopaedics. Since the risks of the development of many diseases such as hip dysplasia, incontinence and heart diseases are breed specific, it is important to report the breeds of the dogs used in studies. Besides, on the occurrence and severity of diseases, breeds may also have effects on parameters like treatment outcomes, side effects, survival time or recurrences.

The age and the weight of the dogs often were documented as a range, mean or median. Standard deviations or quartiles or individual data were not given in all articles, which does not allow the reader to get an impression of whether particularly old or young animals were included in the study. Especially in the context of, but not limited to, trials on age dependent diseases or studies with small sample sizes, these data should be available. It is noticeable that in our sample the individual age of the dogs was given in none of the articles on reproduction. For the studies on cardiology, the age of the dogs was given in only one publication. Also, in the majority of the articles belonging to the other specialities information about the age was missing. The age of a dog is a crucial confounder to nearly every major cause of mortality,[25] treatment success and side effects and therefore relevant for almost all diseases.

A documentation of a sample size calculation was presented in only few articles. This is in accordance with the findings of Wareham et al.,[26] where only 14.3% reported a sample size calculation and Giuffrida[16] with 22.0%. In addition, in most studies the number of animals was low. This fact was discussed by most authors as a limitation of the study. Nevertheless, an appropriate number of animals should be included in all trails since some authors even regard studies with small sample sizes as unethical because the results are highly prone to bias.[27] Our findings are in accordance with conclusions of Girolamo and Reynders[23] which compared interventional human versus veterinary RCTs and revealed that only 2% of veterinary RCTs reported a power calculation. They also reported that the median sample size for crossover trials was eight patients and stated that this might be due to additional expenses for bigger sample sizes. The low prevalence of rare diseases might also play a role. The median sample size seems to have improved as it is 31 according to this study and 30 animals within the trial of Wareham et al.[26]

A limitation of this study is that we did not recalculate the power of the studies. A recalculation, however, would not have been reasonable for most studies because main target parameters were not specified for most studies.

Documentation of handling of missing data is lacking in a high proportion of articles. Haimerl et al.[28] stated that this might be due to incomplete reporting and needs not a priori be judged as low quality. In both human and veterinary medicine research articles, key pieces of information are often lacking due to loss or withdrawal of patients or samples and might lead to biased results.[29] In order to prevent a type I (i.e. false positive) error[30] an 'intent-to-treat' (ITT) analysis

should be performed with the help of the CONSORT diagram.[29] If patients had to be excluded or got lost in the follow-up the missing data should be clearly identified in the 'Results' section.[12]

The description of the statistics was adequate in most of the articles examined. In many articles more complex statistical tests were used. This is in contrast to the study of Girolamo and Reynders[23] who found that in veterinary articles mostly just statistical significances were given.

Regarding ethical approvals, it is noteworthy that around 30.5% of the reviewed published clinical trials did not contain appropriate information. About 46.0% of the surgery articles and 38.0% of the reproduction articles did not report ethical approvals. Especially for surgery studies, one should assume that an ethical approval is necessary, due to the interventional character. There might be a difference between academic versus privately assessed studies. The latter may not have to obey the same regulations. This issue was not assessed in this research project but might be interesting for follow-up studies.

When it comes to ownership and written informed consent of the owners, it is remarkable that in research on cardiology far more experimental dogs were used than in the other veterinary specialities. In the field of internal medicine and neurology, the authors, the reviewers or the editors of the journals seem to pay more attention to the documentation of written informed consent of the owners because it was reported for about 52.0% and 75.0% of the clinical trials, respectively. Nevertheless, there seems to be an improvement as Lund et al.[31] found 91.0% of their evaluated studies did not state a written informed consent.

It is important to accept that just because a study has been published it does not necessarily mean it is any good[32] and may have significant insufficiencies regarding the study design or reporting.[28] Nevertheless, veterinary practitioners should rather rely on good and actual peer-reviewed journal articles than on information of questionable quality or potential outdated sources.[33] Evidence-based medicine is nowadays a common and established method in human medicine, while high-quality evidence base is still lacking in many areas of veterinary medicine.[34] The number of RCTs increased in human medicine over the time period from 2006 to 2013 by 16.0%, while in veterinary medicine the amount of RCTs was still low and lacking adequate reporting of key methodological domains.[23] The impact of missing methodological quality has also been reported by Sargeant et al.,[20] as there is evidence that these deficiencies lead to a likelihood of positive outcomes being reported. This publication bias may lead to misinterpretation of research results, and therefore needs to be taken into account when reading papers and especially when working on reviews, systematic reviews and meta-analyses.[35]

To the authors' knowledge, this is the first project assessing the quality of articles in relation to veterinary medicine specialities. It seems that research in different specialities is influenced by different factors, which cannot be deduced by the presented evaluation results. Nevertheless, these differences provide important research approaches. After all, it needs to be stated that in all specialities methodology and reporting of research results needs to be improved. Although reporting checklists are available,[36] such as ARRIVE for animal research or STROBE for observational studies, which seem to improve the recording of RCTs,[37] there are still deficits present. It can be assumed that these checklists are not consulted to the full extent by some authors and reviewers. This is in accordance with the findings of a study by Grindlay et al.[38]

In order to improve the quality of scientific literature, it is important that authors, reviewers and journal editors pay attention to proper reporting. To support this, reporting guidelines should be implemented within education of veterinary students and researchers. In order to achieve better case management in veterinary practice, the recently published evidence-based veterinary medicine manifesto[2] should be heeded by all veterinarians and researchers.

The results of this study are in accordance with earlier studies, which appraised the quality of published literature and detected deficiencies.[11,17,39] The overall quality of the studies seems to have improved slightly but there are still some attributes such as sufficient sample size, missing data handling and ethical approvals, which need further attention.

Limitations of the own study

There are some limitations of the present study. Even though there was a pretesting with three raters assessing study quality, the investigation was performed by just one person, which may have led to bias. This approach, however, has been used in several other studies before.[17,40,41] Furthermore, the person who evaluated the literature was not blinded to any manuscript details during the evaluation, which potentially may have led to biased interpretation. Lack of blinding may lead to biased assessment in terms of geographical origin or gender of the authors. It has been shown, for example, that human medicine studies from Asia are five times more likely to be rejected from publication in a journal than studies from European or American countries.[42] In addition, Wareham et al.[39] found that RCTs are more likely to be published if they had pharmaceutical industry funding or involvement. While Hopewell et al.[43] found that studies with positive outcomes are more likely to be published. Therefore, the selection of the studies used for this literature search may have been biased based on a publication bias.

Another limitation is the relatively small sample size of 25 articles per speciality. Since a number of 25 articles per speciality led to a total number of 150 articles eligible for a throughout assessment, the inclusion of more literature was not possible within this project. In that regard it may be worthwhile to re-evaluate some

of the presented speciality-specific findings on a larger scale with a high number of articles and to start scoping reviews with involvement of librarians.

CONCLUSION

The findings of this study revealed deficits in methodology and reporting of studies published in peer-reviewed journals in general, with moderate variations between different veterinary medicine specialities. In order to provide veterinary practitioners and clinicians reliable, valid and concise information, authors, reviewers and journal editors should pay attention to proper design and reporting by making use of the different developed guidelines. According to our findings, authors should pay more attention to aspects such as sample size calculation, details of the animals such as breed, housing and feeding, inclusion and exclusion criteria and handling of missing data. Even if there is no data missing, this should be mentioned in the paper for clarity.

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ETHICAL APPROVAL

Since no animals were used in context of this manuscript, no ethical permit was required.

AUTHOR CONTRIBUTIONS

All authors drafted and revised the manuscript.

CONFLICT OF INTERESTS

None of the authors of this paper has a financial or personal relationship with other people or organisations that could inappropriately influence or bias the content of the paper.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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