

# Efficacy of an oral chew containing fibre and *Bacillus velezensis* C-3102 in the management of anal sac impaction in dogs

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## Abstract

**Background:** Anal sac impaction is common in dogs. Manual expression may be effective, yet recurrence can be problematic. To facilitate physiological emptying of the sacs, it is important to maintain bulky stool consistency.

**Objectives:** The study evaluated if supplementation with a complementary feed product formulated as a chew containing *Bacillus velezensis* C-3102 and fibre sources, reduced anal sac impaction recurrence.

**Animals:** Thirty-five client-owned dogs with anal sac impaction were enrolled.

**Materials and Methods:** Prospective, randomised, negative controlled field clinical trial with 22 dogs receiving the chew orally for 90 consecutive days and 13 dogs with no treatment. Dogs were evaluated on Day (D) 30, 60, 90 and 120 for the presence of clinical signs of anal sac impaction and the need to empty the sacs. Any animal that required manual expression of the sacs was classified as a failure and was withdrawn from the study.

**Results:** The cumulative percentage of failures in the untreated group increased steadily from the first follow-up visit on D30 (15%) to the last visit on D120 (61.5%). However, in the group receiving the chew the cumulative percentage of failures increased at a much slower rate and stabilised at 19% from the D90 visit (last administration day) until the end of the study on D120, with statistically significant differences ( $p=0.025$ ). Animals receiving the chew also showed reduction in clinical signs.

**Conclusion and Clinical Relevance:** The probiotic and fibre chew was a safe and effective management option for recurrent anal sac impaction in dogs.

## KEYWORDS

anal sacs, *Bacillus velezensis*, dogs, probiotics

## INTRODUCTION

The dog's anal sacs are lined with apocrine sudoriparous and sebaceous glands that secrete into the sac's lumen.<sup>1</sup> Physiologically, anal sacs are emptied by muscular contractions and stool pressure,<sup>2,3</sup> yet domestication and selective breeding have reduced the contracting ability of the surrounding muscles. When secretions do not empty normally, the sacs become impacted, predisposing to anal sac disease,<sup>4</sup> which is common in dogs.<sup>5–8</sup> Typical clinical signs of anal sac

impaction are scooting, licking or biting of the perianal area, tenesmus and tail chasing.

The efficacy of medical treatment of anal sac disease is poorly described in the literature.<sup>9,10</sup> Manual expression alone may be effective to relieve immediate impaction,<sup>11</sup> but recurrence remains a problem.<sup>12</sup> Stool quality and diet type have been described as risk factors.<sup>5,13</sup> Fibre-rich diets accelerate passage and increase the volume and water-holding capacity of rectal contents; hence, they have traditionally been investigated for the management of anal sac disease, although with limited success.<sup>4,14</sup>

In addition, supplementation with *Bacillus velezensis* C-3102 increases gut bacterial diversity leading to predominance of those producing metabolites that enhance fat and carbohydrate digestibility. This ultimately promotes gut health by reducing gut ammonia and increasing short-chain fatty acids (SCFAs), improving faecal quality.<sup>15–18</sup>

ProGlan (Ecuphar/Animalcare group) is a complementary feed product containing *B. velezensis* C-3102 together with soluble and insoluble fibre and antioxidants. The combination of these ingredients is designed to maintain adequate gastrointestinal function and a healthy gut microbiome, enhancing stool bulk and consistency.<sup>15–17</sup> Therefore, the aim of this study was to evaluate the efficacy of this product as a management option in the reduction of anal sac impaction recurrence in dogs.

## MATERIALS AND METHODS

### Ethics

The study was conducted in compliance with the VICH guideline for Good Clinical Practice.<sup>19</sup> The protocol satisfied national regulatory and animal welfare standards and requirements. All dog owners signed a consent form and could withdraw their dog from the study at any time.

Data were collected using a paper-based data collection system. Following data entry in an Excel spreadsheet, a 100% data quality control was performed to compare the raw data versus data listing outputs.

### Study design

Prospective, multisite, randomised, controlled, parallel-group field study.

### Animals

At each veterinary practice, a registered veterinary surgeon was responsible for animal recruitment and group

allocation. Dogs of different weights, any breed and both sexes could be enrolled in the study. Dogs were considered eligible for the study if they were diagnosed with anal sac impaction and met all of the inclusion and none of the exclusion criteria described in Table 1. Day (D)0 was defined as the day of inclusion and product administration starting day.

Any dog could be withdrawn from the study in case of unsatisfactory response requiring manual expression of the anal sacs; presence of perianal inflammation, discharge or fistulae; a major protocol deviation; poor chew intake; withdrawal of the owner's consent; or occurrence of an adverse event (AE) that could interfere with the evaluation of the study results or required stopping product administration. Supplementation with the product was stopped at the time of withdrawal and no further assessments were performed. Concomitant treatment with antimicrobials or corticosteroids was not permitted throughout the study.

### Product administration

Dogs were randomly allocated into two groups in a 2:1 ratio to receive either ProGlan (Ecuphar/Animalcare group), a chew containing *B. velezensis* C-3102  $3.45 \times 10^{10}$  cfu/g, apple pectin and pumpkin as a fibre source, as well as *Echinacea purpurea*, vitamin C and natural tocopherol extracts (vitamin E) (treated group) or no treatment (negative control group). The random allocation was implemented using sequentially coded boxes following a previously defined randomisation list provided at each site. Veterinary surgeons were responsible for the preparation and dispensing of the study product as well as product accountability.

The chew was administered orally according to dog weight label instructions: <5 kg, half a chew per day; 5–10 kg, one chew; 11–20 kg, two chews; 21–30 kg, three chews; and >30 kg, four chews. The chews were administered by the owner at home once daily for 90 consecutive days. For the first 7 days, half the

**TABLE 1** Inclusion and exclusion criteria for participation of client-owned dogs suffering from anal sac impaction in the study.

Inclusion criteria	Exclusion criteria
Client-owned dogs presenting at the veterinary practice with anal sac impaction with no signs of inflammation, infection or abscessation	Treatment with topical corticosteroids, antibiotics and or antifungal agents for the last 2 weeks or orally for the last 4 weeks
Dogs that have had their anal sacs emptied at least three times in the last 12 months	Long-acting corticosteroids administered for the previous 8 weeks
Clinically healthy dogs, other than the anal sac impaction, confirmed by a thorough physical examination and the presence of associate clinical signs such as scooting, licking of the perianal area, tenesmus or tail chasing	Dogs with underlying skin or gastrointestinal conditions requiring treatment
No further treatment other than manual emptying, such as flushing and or administration of local or systemic antibiotics or anti-inflammatory drugs	Dogs likely to require further treatment or anal sac surgery during the study period
The sacs had to be impacted yet otherwise were easily emptied by the veterinary surgeon	Animals presenting perianal discharge, redness of the tail or anal area
The content of the sacs had to look normal, with no signs of pathological abnormality	Animals exhibiting aggressive or frightened behaviour that causes difficulty in clinical examinations
	Animals with previous history of anal sac infection or abscessation

recommended dose was given to allow the dog to adjust to the increased dietary fibre. Then, the full recommended dose was given for the rest of the administration period. Dogs allocated to the negative control group did not receive any treatment. Owners were instructed to guarantee free access to water throughout the study and asked to daily register product administration compliance, assessing if the chews were well-accepted by the dogs.

## Efficacy assessment

At each veterinary practice, a single veterinary surgeon was responsible for all efficacy assessments. On D0 the veterinary surgeon assessed both anal sacs and recorded the presence of clinical signs typically associated with anal sac impaction (scotching; licking or biting the perianal area or tail-base region; tail chasing; pain on palpation; tenesmus) as reported by the owners. Anal sac status, such as size (normal or enlarged), consistency (normal or firm) and the presence of pain on palpation or signs of inflammation, discharge or fistulae also were evaluated. After clinical evaluation, the veterinary surgeon manually expressed one or both anal sacs, assessing the difficulty, the amount (normal or increased) and the gross appearance and consistency (normal; slightly thick and brown; very thick pasty and brown) of the anal sac contents.

At each follow-up visit on D30 ( $\pm 5$ ), D60 ( $\pm 5$ ), D90 ( $\pm 5$ ) and D120 ( $\pm 5$ ), the veterinary surgeon recorded the presence of clinical signs as reported by the owners and evaluated the anal sac status as in the initial visit. If the veterinary surgeon considered the anal sacs to be impacted, manual expression was performed, assessing the difficulty and the gross appearance of the contents as in the initial visit. The follow-up visit on D120 (30 days after last product administration) assessed any relapse on anal sac impaction.

Animals requiring manual anal sac expression at any time point during the study were classified as failures (primary efficacy outcome measure) and were withdrawn from the study.

Secondary efficacy outcome measures were the presence of clinical signs associated with anal sac impaction as reported by the owners at any follow-up visit.

## Safety assessment

Safety was assessed by recording any AE irrespective of its nature and severity, or whether or not it was product related. Owners were informed about the possible AEs related to the product and were instructed to observe the animals daily and to immediately report any suspected AE to the veterinary surgeon. Owing to the nature of the product, safety assessments were focussed on possible changes in faecal frequency and consistency.

## Sample size calculation

The sample size was calculated with respect to the primary efficacy outcome measure using an online statistical calculator.<sup>20</sup> As the protocol included a group of dogs that would not receive any treatment, and despite that the veterinary surgeon could withdraw any dog from the study at any time, it was decided to reduce the size of the negative control group to the minimum that allowed a reliable statistical comparison. Therefore, the number of dogs in the negative control group was calculated to be one half of the treated group.

Based on previous results described by James et al.,<sup>12</sup> it was hypothesised that 81% of the untreated dogs would require manual anal sac expression at some point during the study. Considering the desired proportion 2:1 of dogs in the treated and negative control groups, a sample size of 22 and 11 dogs would be required, respectively. This sample size would provide 80% power to detect significant differences in the proportion of dogs requiring anal sac manual expression (primary efficacy outcome measure) with a 0.05 two-sided significance level.

## Statistical analysis

The analysis of the efficacy parameters was performed with the program SIGMAPLOT (v13.0; Systat Software).

Demographic and baseline data descriptive evaluation was carried out on all enrolled animals to confirm the balanced distribution of dogs in the two groups. Descriptive statistics of the data are presented as the mean  $\pm$  SD or median (range) for the continuous variables, such as weight and age, and as percentages for categorical variables. The statistical analysis for the primary efficacy variable was performed with all animals that were randomised and had at least an efficacy assessment on D30. After the first efficacy assessment, the classification at the time of withdrawal from the study was maintained in all subsequent time points subjected to the last observation carried forward (LOCF) method.

For the analysis of safety parameters, all enrolled animals that received at least one dose of the product were included.

Differences between groups for categorical variables were evaluated by means of the appropriate test (chi-square test or Fischer's exact test). For the primary efficacy endpoint, relative risk (RR), odds ratio (OR), Kaplan–Meier survival plots as well as survival times with a 95% confidence interval (CI) were calculated. For the secondary variables, percentages were compared between groups considering the actual number of dogs in the study at each time point. All statistical tests were performed two-sided at an overall 5% ( $p < 0.05$ ) level of significance.

## RESULTS

### Study population

Thirty-five dogs, 20 females (16 spayed and 4 entire) and 15 males (8 neutered and 7 entire) were included in the study. Twenty-two dogs received the chews and 13 dogs received no treatment. See Table 2 for the baseline characteristics.

Thirteen breeds were represented in this study, in addition to 13 mixed-breed dogs. The most represented breeds were Yorkshire Terrier ( $n=4$ ), Labrador Retriever ( $n=4$ ), Beagle ( $n=3$ ) and Chihuahua ( $n=2$ ) and one dog each for the following breeds: Spitz, French Bulldog, Bichon Frisé, Xoloitzcuintle, Cocker Spaniel, Maltese Bichon, hound, Greyhound and Pug.

Review of the dogs' medical history showed that 66% of the dogs had their anal sacs manually expressed at least four times or more in the previous 12 months (73% and 54% in the treated and the control group, respectively). Examination of anal sacs on D0 before the start of product administration revealed that most dogs presented with both anal sacs enlarged (82% and 54% in the treated and the control group, respectively). In most cases, the consistency was normal and no signs of pain or inflammation

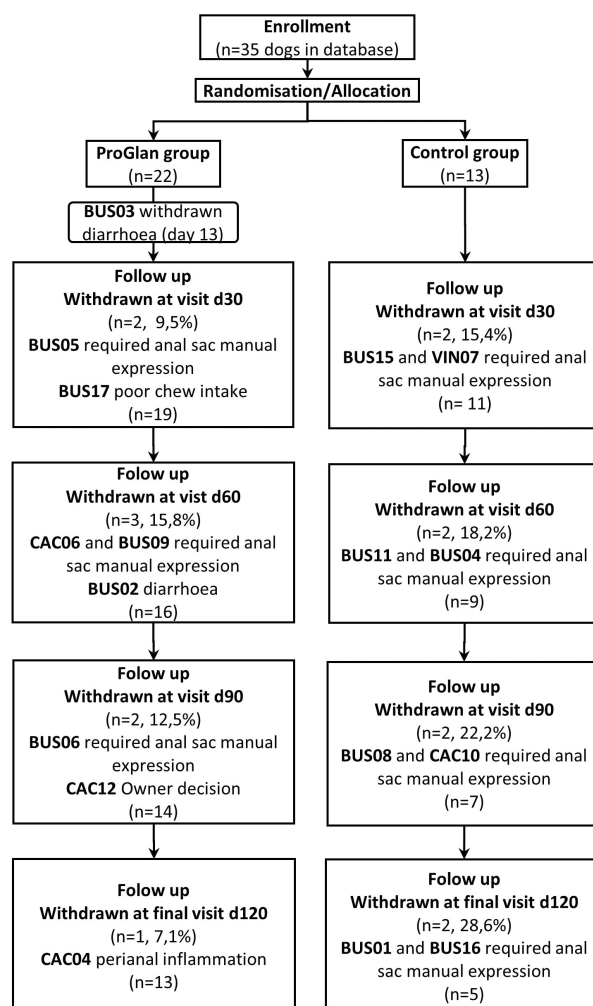
were observed, in agreement with no other anal sac pathological evidence present other than impaction and no further treatment needed other than manual expression.

When anal sacs were manually expressed on D0, it was observed that for most dogs it was easy and the contents were predominantly slightly thick and with brown appearance.

A total of 17 dogs were withdrawn from the study at different time points (9 in the treated group and 8 in the negative control group). One treated dog was withdrawn before the first visit, on D13, owing to diarrhoea. As this dog did not have any efficacy assessment, it was not included in the efficacy calculations. On D30, 3 dogs needed manual expression of the anal sacs and 1 dog was withdrawn as a consequence of poor product acceptance. On D60, 4 dogs required anal sac manual expression and 1 dog was withdrawn as a consequence of diarrhoea. At the visit on D90, 3 dogs needed anal sac manual expression and 1 dog was withdrawn as a consequence of owner decision. Finally, at the last visit on D120, 2 dogs needed manual expression of the anal sacs and 1 dog was withdrawn as a consequence of perianal inflammation. For a graphic of the withdrawal history, see the flow chart in Figure 1.

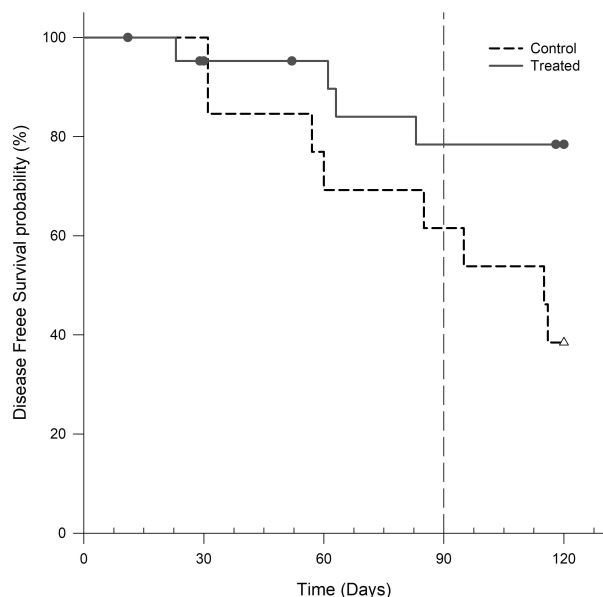
**TABLE 2** Distribution between groups for the demographic characteristics.

	ProGlan, $n=22$	Negative control, $n=13$
<b>Sex, <math>n</math> (%)</b>		
Male	9 (40.9%)	6 (46.1%)
Entire	4	3
Neutered	5	3
Female	13 (59.1%)	7 (53.8%)
Entire	4	0
Neutered	9	7
<b>Age, years</b>		
Mean (SD)	6.88 (4.1)	7.54 (3.8)
Range	1–15	2–14
<b>Body weight, kg</b>		
Mean (SD)	12.62 (7.4)	14.77 (11.1)
Range	3.1–30	4–41
<b>Breed, <math>n</math> (%)</b>		
Mongrel	7 (31.8%)	6 (46.1%)
Purebred	15 (68.2%)	7 (53.8%)
<b>Number of times sacs emptied in the last 12 months (%)</b>		
3	6 (27.2%)	6 (46.1%)
4	6 (27.2%)	4 (30.8%)
5	4 (18.2%)	2 (15.4%)
>5	6 (27.2%)	1 (7.7%)
<b>Clinical signs</b>		
Scotting	15 (68.2%)	7 (53.8%)
Licking/biting	13 (59.1%)	7 (53.8%)
Tenesmus	9 (40.1%)	3 (23.1%)
Tail chasing	9 (40.1%)	6 (37.5%)



**FIGURE 1** Flow chart showing number of dogs recruited, allocated to each group and analysed.





**FIGURE 2** Kaplan–Meier disease-free survival curve for dogs receiving ProGlan or untreated dogs until the need of anal sac emptying. Day 90 is the last administration day. Symbols indicate censored data.

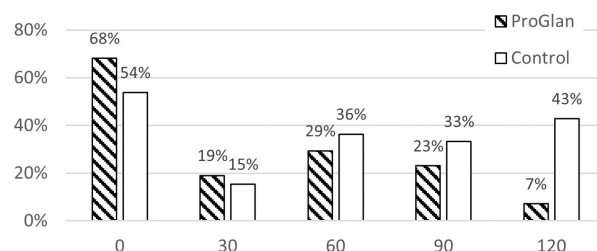
## Efficacy evaluation

The cumulative percentage of dogs requiring anal sac manual expression throughout the study and therefore classified as failures in each group is depicted in Figure 2.

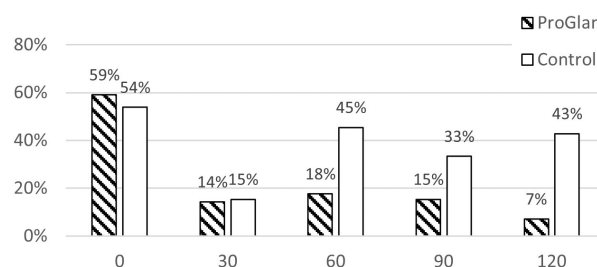
The cumulative percentage of failures in the negative control group increased steadily from the first follow-up visit on D30 to the last visit on D120, where 61.5% of the dogs (8 of 13) had been withdrawn because they had required manual anal sac expression. In the group receiving the chew, the cumulative percentage of failures increased at a much slower rate and stabilised at 19% of the dogs (4 of 21) at the D90 visit (last administration day) until the end of the study on D120. The difference in the percentage of failures between groups on D120 was statistically significant ( $p=0.025$ ) with a RR of 2.1 (95% CI=1.026–4.316) and OR of 6.8 (95% CI=1.43–32.4), indicating that an untreated dog was at least twice as likely to need manual expression of anal sacs than a dog receiving the chew.

The most prevalent clinical signs observed during the study were scooting and licking/biting of the perianal area. As shown in Figure 3, animals in the treated group showed a gradual reduction in scooting and by the end of the study (D120) only 7.1% of the remaining dogs in this group had this clinical sign. By contrast, animals in the negative control group gradually showed an increase in signs of scooting over time with 42.9% of the remaining dogs showing this sign on D120 (almost reaching values observed before manual expression of anal sacs on D0 (53.8%)).

A similar pattern was observed in the percentage of dogs showing signs of licking or biting the perianal area (see Figure 4).



**FIGURE 3** Evolution of the percentage of dogs showing signs of scooting per group throughout the study.



**FIGURE 4** Evolution of the percentage of dogs showing signs of licking or biting the perianal area per group throughout the study.

## Safety evaluation

In the treated group, one dog developed diarrhoea during the first month of administration when the full dose was administered and the owner decided to withdraw the animal from the study. By study D60, three dogs had softer faeces at some point, yet it was not considered necessary to stop product administration. By D90, two dogs were reported to have softer faeces very often, with no need to stop product administration. Finally, by the end of the study (D120), 30 days after the end of product administration, two dogs were reported to have softer faeces and diarrhoea at some point. According to the owners, the chew was well-accepted with only one animal not accepting the product voluntarily.

## DISCUSSION

Non-neoplastic anal sac disease can include impaction, inflammation with or without infection and abscessation. In our study we included only anal sac impaction cases to be able to assess the efficacy of the probiotic and fibre supplement as a single management tool after manual expression. However, the need for additional treatments, such as sac flushing, infusions and anti-inflammatory drugs should be evaluated when signs of sacculitis are observed.<sup>21,22</sup>

To the best of our knowledge, this is the first clinical trial evaluating the efficacy of a product specifically designed for anal sac impaction management. The benefits reported in this study can be attributed to the several modes of action (MoAs) of the ingredients. The probiotic *B. velezensis* C-3102 has been shown to provide many benefits in terms of gut health. In a strain-dependent

manner, *B. velezensis* C-3102 improves faecal consistency, with a tendency to reduce flatulence and faecal fermentation.<sup>15–18</sup> The fermentative nature of *B. velezensis* C-3102 is seen in the reduction of faecal pH and ammonium.<sup>17–19</sup> The *Bacillus* genus is part of healthy anal sac microbiota,<sup>23</sup> adding to its microbial diversity and is associated with protection against pathogens and stimulation of host immune response.<sup>24</sup>

The inclusion of dietary fibre from pumpkin seeds, which are a natural source of nutrients, minerals, vitamins and bioactive compounds (carotenoids, phenolic acids, flavonoids and tocopherols) supports bulking of the stools in the colon.<sup>25</sup> Most of the nondigestible fibre is fermented in the colon where it pulls water into the digestive tract, binding and bulking faeces to the fibre and thus improving faecal transit and favouring natural emptying of anal sacs.<sup>4,14</sup> Additionally, apple pectin, as a source of dietary soluble fibre, slowly dissolves into a gel-like substance in the gastrointestinal tract, absorbing intestinal fluids. Pectin provides diverse health benefits including improvement of physical bowel function and increasing faecal mass.<sup>26</sup> Together with other carbohydrate sources, pumpkin fibre and *E. purpurea* serve as prebiotics for *B. velezensis* C-3102 and the commensal gut microbiota. The ability of *B. velezensis* C-3102 to ferment fibre and other plant material in the colon results in host-beneficial production of metabolites, such as SCFAs,<sup>15,16</sup> which may promote beneficial microbiota proliferation,<sup>15</sup> reducing dysbiosis. SCFAs, including acetate, propionate and butyrate, have an anti-inflammatory effect both in the intestine and in the skin.<sup>27</sup>

Additionally, the antioxidant effect of vitamins C and E as well as *E. purpurea* have been reported to have immunomodulatory activities with anti-infective, anti-inflammatory and antioxidative properties,<sup>28,29</sup> which may be beneficial in stressful situations, such as gastrointestinal disorders, potentially leading to anal sac disease.

Plant-based antioxidants have shown duplibiotic properties, defined as unabsorbed substrates modulating the gut microbiota by both antimicrobial and prebiotic MoAs, which also have been reported for polyphenolic antioxidants such as *E. purpurea* promoting beneficial gut bacteria conferring health benefits.<sup>30</sup>

The results of ProGlan supplementation demonstrated in this study are attributed to improved digestion and better faecal quality favouring stool bulking and gastrointestinal emptying, allowing natural anal sac emptying. However, several limitations should be considered. Faecal quality and consistency were not directly assessed in this study. Moreover, gastrointestinal microbiome evaluation was not performed, and the microbiological impact is assumed based on previous clinical studies in dogs on *B. velezensis* C-3102.<sup>15–18</sup> Another limitation of the study is the small sample size; however, this was statistically sufficient to prove clear positive effects of the product in the physiological anal sac emptying. Additionally, variability in the competence of the veterinary surgeons to empty the anal sacs completely should be taken into consideration. Finally, recurrence of anal sac impaction and inflammation has been reported to occur after 2–5 months.<sup>5,12</sup> Therefore,

longer studies with a larger number of animals would be needed to confirm these results in the long term. Furthermore, the link between anal sac microbiota, including *B. velezensis* C-3102 and skin health<sup>31</sup> also may be better described with a larger sample size analysing the anal sac and faecal microbiome.

In conclusion, this study demonstrates that ProGlan was safe and effective for reducing the risk of anal sac impaction over a period of 4 months. With its good palatability it provides an option for the prevention and management of anal sac disease.

## AUTHOR CONTRIBUTIONS

**Marta Salichs:** Conceptualization; writing – original draft; methodology; validation; visualization; supervision. **Shea Beasley:** Writing – original draft. **Josep Homedes:** Conceptualization; writing – original draft; validation; visualization; formal analysis.

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## CONFLICT OF INTEREST STATEMENT

Marta Salichs and Josep Homedes are full employees of Ecuphar Veterinaria SLU (Animalcare group). Shea Beasley is a consultant for Animalcare group.

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## Zusammenfassung

**Hintergrund:** Eine Verstopfung der Analbeutel tritt bei Hunden häufig auf. Ein manuelles Ausdrücken kann wirksam sein, wobei allerdings ein ständiges Wiederauftreten ein Problem darstellt. Um die physiologische Entleerung der Analbeutel zu erleichtern, ist es wichtiger eine feste Kotkonsistenz zu erhalten.

**Ziele:** Die Studie evaluierte, ob eine Supplementierung mit einem komplementären Futterprodukt, welches als Kauartikel formuliert war und *Bacillus velezensis* C-3102 und Ballaststoff-Quellen enthielt, das Wiederauftreten der Analbeutelverstopfung reduzierte.

**Tiere:** Fünfunddreißig Hunde in Privatbesitz mit einer Analbeutelverstopfung wurden in die Studie aufgenommen.

**Materialien und Methoden:** Es handelt sich um eine prospektive, negativ kontrollierte Feldstudie mit 22 Hunden, die den Kauartikel an 90 aufeinanderfolgenden Tagen *per os* erhielten und 13 Hunden ohne Behandlung. Die Hunde wurden an den Tagen (D)30, 60, 90 und 120 untersucht, um eine Analbeutelverstopfung und die Notwendigkeit die Analbeutel zu entleeren, festzustellen. Jedes Tier, bei dem eine manuelle Entleerung der Analbeutel nötig war, wurde als Misserfolg betrachtet und aus der Studie ausgeschieden.

**Ergebnisse:** Der kumulative Prozentsatz der Misserfolge in der Gruppe der unbehandelten Hunde nahm nach dem ersten Follow-Up Besuch am D30 (15%) bis zum D120 (61,5%) stetig zu. In der Behandlungsgruppe hingegen nahm der kumulative Prozentsatz der Misserfolge viel langsamer zu und stabilisierte sich bei 19% nach der Kontrolle am D90 (letzter Tag der Aufnahme) bis zum Studienende am D120, was statistisch signifikant war ( $p=0,025$ ). Die Tiere in der behandelten Gruppe zeigten ebenfalls eine Reduzierung der klinischen Zeichen.

**Schlussfolgerung und klinische Bedeutung:** Der probiotische und Ballaststoff-reiche Kauartikel war eine sichere und wirksame Management Option für eine wiederkehrende Analbeutelverstopfung bei Hunden.

## Resumo

**Contexto:** A impactação do saco anal é comum em cães. A expressão manual pode ser eficaz, mas a recorrência costuma ser problemática. Para facilitar o esvaziamento fisiológico dos sacos, é importante manter as fezes volumosas.

**Objetivos:** O estudo avaliou se a suplementação com um produto alimentar complementar formulado como um comprimido mastigável contendo *Bacillus velezensis* C-3102 e fontes de fibras reduziu a recorrência da impactação do saco anal.

**Animais:** Trinta e cinco cães de clientes com impactação do saco anal foram incluídos.

**Materiais e métodos:** Ensaio clínico de campo prospectivo, randomizado e controlado negativamente com 22 cães recebendo o comprimido mastigável por via oral durante 90 dias consecutivos e 13 cães sem tratamento. Os cães foram avaliados nos dias (D) 30, 60, 90 e 120 quanto à presença de sinais clínicos de impactação do saco anal e à necessidade de esvaziar os sacos. Qualquer animal que necessitasse de expressão manual dos sacos foi classificado como falha e foi retirado do estudo.

**Resultados:** A porcentagem cumulativa de falhas no grupo não tratado aumentou de forma constante da primeira visita de acompanhamento no D30 (15%) até a última visita no D120 (61,5%). No entanto, no grupo tratado, a porcentagem cumulativa de falhas aumentou a uma taxa muito mais lenta e se estabilizou em 19% da visita D90 (último dia de administração) até o final do estudo no D120, com diferenças estatisticamente significativas ( $p=0,025$ ). Os animais no grupo tratado também apresentaram redução nos sinais clínicos.

**Conclusão e relevância clínica:** O comprimido oral com probiótico e fibra foi uma opção de tratamento segura e eficaz para impactação recorrente do saco anal em cães.

## 摘要

**背景:** 犬常见的肛门囊嵌塞。手动挤压可能有效,但复发可能会成为问题。为了促进肛门腺的生理性排空,保持粪便的厚实质地很重要。

**研究目的:** 本研究旨在评估一种以咀嚼片形式制成的补充饲料,其中含有巴氏杆菌C-3102和纤维来源,是否能减少肛门囊嵌塞的复发。

**动物:** 共纳入35只由宠物主人饲养的肛门囊嵌塞犬。

**材料与方法:** 采用前瞻性、随机、阴性对照的野外临床试验,22只犬口服咀嚼片连续90天,13只犬不接受治疗。在第30天、第60天、第90天和第120天对犬进行评估,以确定是否存在肛门囊嵌塞的临床症状以及是否需要排空肛门腺。任何需要手动排空肛门腺的动物都被归类为失败病例,并从研究中退出。

**结果:** 未治疗组的累积失败率从第30天的第一次随访(15%)稳步增加至第120天的最后一次随访(61.5%)。然而,在治疗组中,累积失败率的增加速度要慢得多,从第90天的随访(最后一次给药日)开始至第120天的研究结束,累积失败率稳定在19%,具有统计学意义的差异( $p=0.025$ )。治疗组动物的临床症状也有所减轻。

**结论及临床意义:** 对于犬的复发性肛门囊嵌塞,益生菌和纤维咀嚼剂是一种安全有效的管理方案。

## Résumé

**Contexte:** L'impaction du sac anal est fréquente chez les chiens. L'expression manuelle peut être efficace, mais la récurrence peut être problématique. Pour faciliter la vidange physiologique des sacs, il est important de maintenir la consistance des selles volumineuses.

**Objectifs:** L'étude évalue si la supplémentation avec un produit alimentaire complémentaire formulé comme une bouchée à mâcher contenant *Bacillus velezensis* C-3102 et des sources de fibres, réduit la récurrence de l'impaction du sac anal.



**Animaux:** Trente-cinq chiens appartenant à des clients et présentant une impaction du sac anal sont recrutés.

**Matériels et méthodes:** Essai clinique prospectif, randomisé, contrôlé négativement sur le terrain avec 22 chiens recevant la bouchée à mâcher par voie orale pendant 90 jours consécutifs et 13 chiens ne recevant aucun traitement. Les chiens sont évalués aux jours 30, 60, 90 et 120 concernant la présence de signes cliniques d'impaction du sac anal et la nécessité de vider les sacs. Tout animal pour lequel l'on a dû exprimer manuellement les sacs anaux est considéré comme un échec et est retiré de l'étude.

**Résultats:** Le pourcentage cumulé d'échecs dans le groupe non traité augmente régulièrement depuis la première visite de suivi à J30 (15%) jusqu'à la dernière visite à J120 (61,5%). Cependant, dans le groupe traité, le pourcentage cumulé d'échecs augmente beaucoup plus lentement et se stabilise à 19 % entre la visite de J90 (dernier jour d'administration) et la fin de l'étude à J120, avec des différences statistiquement significatives ( $p=0,025$ ). Les animaux du groupe traité montrent également une réduction des signes cliniques.

**Conclusion et pertinence clinique:** Les bouchées à mâcher à base de probiotiques et de fibres constituent une option de gestion sûre et efficace de l'impaction récurrente du sac anal chez les chiens.

## 要約

**背景:** 肛門囊閉塞は犬では一般的である。用手処置は効果的であるが、再発が問題となることがある。肛門囊の生理的排出を促進するためには、高高い便の硬さを維持することが重要である。

**目的:** 本研究では、*Bacillus velezensis* C-3102および繊維源を含む咀嚼用補完飼料を給与することで、肛門囊閉塞の再発が減少するかどうかを評価した。

**対象動物:** 肛門囊閉塞を有する35頭のオーナー所有犬を登録した。

**材料と方法:** 前向き、無作為化、陰性対照野外臨床試験で、22頭の犬に90日間連続で噛みものを経口投与し、13頭の犬には無処置とした。犬は30日目、60日目、90日目、120日目に、肛門囊閉塞の臨床徴候の有無と肛門囊を空にする必要性について評価された。肛門囊を手で開口する必要があった動物はすべて失敗と分類され、試験から除外された。

**結果:** 未治療群における不成功の累積割合は、最初の追跡調査から試験開始30日目(15%)、120日目(61.5%)の最終調査まで着実に増加した。しかし、投与群では、試験開始90日目(最終投与日)から120日目の試験終了まで、失敗の累積割合ははるかに遅い割合で増加し、19%で安定し、統計学的に有意な差が認められた( $p=0.025$ )。投与群の動物は臨床症状も軽減した。

**結論と臨床的意義:** プロバイオティクスおよび繊維源を含む咀嚼用補完飼料は、犬の再発性肛門囊閉塞に対する安全かつ効果的な管理選択肢であった。

## RESUMEN

**Introducción:** La impactación de los sacos anales es común en los perros. La expresión manual puede ser eficaz, pero la recurrencia puede ser problemática. Para facilitar el vaciado fisiológico de los sacos, es importante mantener una consistencia de heces voluminosas.

**Objetivos:** El estudio evaluó si la suplementación con un producto alimenticio complementario formulado como un masticable que contiene *Bacillus velezensis* C-3102 y fuentes de fibra, redujo la recurrencia de la impactación de los sacos anales.

**Animales:** Se admitieron treinta y cinco perros con impactación de los sacos anales de propietarios particulares.

**Materiales y métodos:** Ensayo clínico de campo prospectivo, al azar, con controles negativos en 22 perros que recibieron el masticable por vía oral durante 90 días consecutivos y 13 perros sin tratamiento. Los perros fueron evaluados los días (D) 30, 60, 90 y 120 para detectar la presencia de signos clínicos de impactación de los sacos anales y la necesidad de vaciar los sacos. Cualquier animal que requirió la expresión manual de los sacos fue clasificado como un fracaso y fue retirado del estudio.

**Resultados:** El porcentaje acumulado de fracasos en el grupo no tratado aumentó de forma constante desde la primera visita de seguimiento el día 30 (15 %) hasta la última visita el día 120 (61,5 %). Sin embargo, en el grupo tratado el porcentaje acumulado de fracasos aumentó a un ritmo mucho más lento y se estabilizó en el 19 % desde la visita el día 90 (último día de administración) hasta el final del estudio el día 120, con diferencias estadísticamente significativas ( $p=0,025$ ). Los animales del grupo tratado también mostraron una reducción de los signos clínicos.

**Conclusión y relevancia clínica:** El probiótico y la fibra masticables fueron una opción de tratamiento segura y eficaz para la impactación recurrente de las glándulas anales en perros.