Critical appraisal – Randomised controlled trial questions

Introduction	
Are the aims clearly stated?	Yes: to compare budesonide and prednisone for induction therapy of IBD in dogs by using IBD activity scores and evaluating frequency and severity of owner-reported adverse effects.
Methods	
Is the study design suitable for the aims?	Yes
Which population was studied?	40 dogs of at least 3kgs weight diagnosed with idiopathic inflammatory bowel disease on the basis of: persistent (>3 weeks duration) or recurrent gastrointestinal signs AND inadequate response to dietary and symptomatic therapies alone AND thorough diagnostic evaluation with exclusion of other causes of gastroenteritis AND histopathological evidence of mucosal inflammation.
Were the treatments randomly allocated? If yes, how was the randomisation done?	Yes. Computed generated schedule into one of two treatment groups. Randomisation was done by a technician who was blinded to everything apart from body weight.
Were the groups comparable prior to intervention?	Yes
Was the person who administered the interventions blinded?	Dispenser, owner, histopathologist and CIBDAI scorer were blinded. Unclear whether the study authors who performed clinical examinations and endoscopy were blinded.
Is it clear what measurements were carried out in the study?	Yes

Were the correct measurements chosen? Do they reflect (or are they strongly related to) the outcome of interest?	Yes Yes
Were previously established validated methods used to make the measurements? (e.g. Glasgow pain score, International Units etc)	Yes (Canine Inflammatory Bowel Disease Activity Index)
What outcomes were measured?	• Age, sex, breed • At baseline, weeks 3 and 6: complete blood count; biochemistry; urinalysis • At baseline and week 6: endoscopic visual findings; endoscopic biopsy histopathology; composite endoscopic biopsy score; calculated Canine Inflammatory Bowel Disease Activity Index (CIBDAI) • Weekly during the trial: owner questionnaire about their dog's attitude and clinical signs, focused on adverse effects • Week 6 only: number of patients in remission (>75% reduction in CIBDAI)
Are the outcomes clinically relevant?	Yes
Were the outcomes assessed blind?	Mostly yes; unclear from methods whether owner questionnaires, endoscopy and clinical examination were performed by blinded clinicians.
Are the statistical methods described?	Yes
Was the statistical significance level stated?	Yes

Was the sample size justified?	They justified why they used so few animals, however they did not use a power calculation to determine their sample size
Was ethical approval obtained?	Doesn't state
Are the methods described in enough detail that you could repeat them?	Yes, though more information on recruitment and the computer randomization method would have been useful.
Results	
Were the basic data adequately described?	Yes for baseline data but only selected outcomes were reported.
Do the numbers add up? Are all subjects accounted for?	Yes Yes
Was the statistical significance (p value) stated in the results? Is this consistent with the methods? (It should be stated in the sample size or power calculation)	Yes Yes
Were any side effects of the intervention reported if applicable?	Yes
What were the main findings/key results?	• 40 dogs were enrolled in the trial, 20 in each arm. • 6 dogs dropped out: 4 dogs in the prednisone group, and 2 in the budesonide group. • Both treatments were effective in reducing CIBDAI scores from baseline with 68.8% of dogs treated with prednisone and 77.8% of dogs treated with budesonide being considered as in remission. • There was no significant difference in the number of dogs in remission between the two treatments (p=0.70).

	• There were no significant changes in the bodyweight of dogs in either group.
Discussion and conclusion	
What do the main findings/key results mean?	Both budesonide and prednisone are effective in the treatment of IBD, though in the UK budesonide is not licensed and therefore should not be recommended under the cascade.
Are the negative findings discussed? How are the negative findings interpreted?	Yes They discussed why dogs were taken out of the study and the challenges associated with dosing budesonide.
Does the discussion reflect the results?	Yes
Interpretation	
What are the clinical implications of this study? Are the subjects in the study similar to those in the BET/your own?	Budesonide is effective at reducing the clinical signs of inflammatory bowel disease, however it is not licensed in the dog and clinicians should be guided by the cascade. Yes
General	
Who funded this study?	Morris Animal Foundation