Critical appraisal – Randomised controlled trial questions

Introduction	
Are the aims clearly stated?	Yes The aim of the study was to evaluate the benefit and efficacy of amoxicillin/clavulanic acid in the treatment of aseptic dogs with HGE
Methods	
Is the study design suitable for the aims?	Yes, this is a randomised controlled trial
Which population was studied?	60 dogs presenting with haemorrhagic gastroenteritis (HGE) at University of Munich, Germany during a specific two year timeframe (Aug 2007 – Sept 2009) The patients were include if they had acute onset bloody diarrhea (<3 days). Dogs were excluded if they had: signs of sepsis, possible aetiology unrelated to HGE (e.g. CKD, parasites, adverse events to drugs, liver disease, pancreatitis, bleeding disorder), the presence of primary enteropathogenic bacteria (e.g. Salmonella, Campylobacter, Yersinia) on faecal culture, parvovirus, Addisons, a history of any drug that may cause mucosal irritation (e.g. NSAIDs, corticosteroids, doxycycline) use in the last week or had been pre-treated with antibiotics. Half of the dogs were treated with amoxicillin/clavulanic acid for 7 days (injections in the hospital tablets at home) the other half received no antibiotics (nothing in the hospital placebo tablets at home). Fluid therapy, gastric antacids ad protectants and treatment to guard against DIC was the same in both groups.

	Dogs were hospitalised for a minimum of 3 days and were discharged if they were not dehydrated, were not vomiting, had no watery diarrhoea and had normal activity levels.
Were the treatments randomly allocated? If yes, how was the randomisation done?	Yes The randomisation was done via computer generated schedule
Were the groups comparable prior to intervention?	Yes
Was the person who administered the interventions blinded?	No, however the person (clinicians and owners) assessing clinical signs/response to treatment were blinded to treatment/placebo group
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)	A newly developed scoring system called the 'canine HE activity index' was used to assess the clinical signs. This is a subjective cumulative score based on appetite, vomiting, stool consistency an frequency and dehydration. This was modified from the canine inflammatory bowel disease index. After discharge from the hospital owners were asked to assess these parameters except for dehydration. This system was not validated.

What outcomes were measured?	HGE activity index Duration of hospitalisation Drop out rates Mortality rates
Are the outcomes clinically relevant?	Yes
Were the outcomes assessed blind?	Yes
Are the statistical methods described?	Yes
Was the statistical significance level stated?	Yes, p=0.05
Was the sample size justified?	No (A retrospective power analysis was conducted to calculate the power of detecting a difference in the dropout proportion between groups.)
Was ethical approval obtained?	It states that the project was undertaken within animal welfare law. There is no mention of ethical approval.
Are the methods described in enough detail that you could repeat them?	Yes
Results	
Were the basic data adequately described?	Yes
Do the numbers add up?	Yes

Are all subjects accounted for?	Yes, all drop outs were described
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, none were observed.
What were the main findings/key results?	There was no significant difference between treatment and placebo groups in terms of the canine HGE index on any day of the study ($p = 0.487$). There was no difference in faecal consistency between groups. A rapid improvement in clinical signs was seen in both groups. The duration of hospitalisation was not significantly different between groups ($p = 0.740$). Median duration of hospitalisation in treatment group was 3 days (range 3-4), median duration of hospitalization in placebo groups was 3 days (range 3-7) The number of drop-outs between groups was not statistically significant. The power to detect a difference was calculated as 58%.
Discussion and conclusion	
What do the main findings/key results mean?	Antibiotics may not be required by dogs with aseptic HGE.
Are the negative findings discussed? How are the negative findings interpreted?	Yes It is suggested that the lack of difference may be attributed to small study size or potentially the

	presence of bacteria present not sensitive to the antibiotic used in this study.
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?	Animals presenting with aseptic HGE may not require antibiotics as part of the overall supportive therapy plan. Yes
General	
Who funded this study?	No funding source stated. Client- funded as part of care plan for University patients