Critical appraisal – Randomised controlled trial questions

Runciman et al. 2009

Introduction	
Are the aims clearly stated?	Yes. The outcome of interest for our BET is not the primary outcome of interest of the study
Methods	
Is the study design suitable for the aims?	Yes – testing diagnosis types, and treatments so trial is appropriate
Which population was studied?	Cows from 6 seasonal dairy herds – those with vaginal discharge (some level of pus) were enrolled into the treatment trial
Were the treatments randomly allocated? If yes, how was the randomisation done?	Yes Coin toss until half of the cows were filled in one group, then rest of the cows were assigned into the other group
Were the groups comparable prior to intervention?	Not much detail given about the different groups
Was the person who administered the interventions blinded?	Not stated, but would be impossible due to nature of administration
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)	Mention studies in the introduction about Metricheck and vaginal examination being less sensitive than ultrasound
What outcomes were measured?	First service to conception interval, submitted to service within 3 weeks/6 weeks/21 weeks of mating start date
Are the outcomes clinically relevant?	Yes
Were the outcomes assessed blind?	Not stated
Are the statistical methods described?	Yes
Was the statistical significance level stated?	Yes – $P<0.05$
Was the sample size justified?	Carried out a sample size calculation
Was ethical approval obtained?	Yes – University of Melbourne
Are the methods described in enough detail that you could repeat them?	Mostly, although some more detail would be nice to have
Results	
Were the basic data adequately described?	Not particularly detailed, no
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?	No
What were the main findings/key results?	Conception to first service (AI) statistically significantly better in the treated group than non-treated group (for VV group p=0.036, not for Metricheck group p=0.15) Proportion of cows pregnant within 6 weeks of mating start date statistically significantly better in the treated group than non-treated group (for both VV p=0.015 and Metricheck p=0.011 groups) Proportion of cows pregnant within 21 weeks of mating start date statistically significantly better in the treated group than non-treated group (for VV group p=0.026, but not for Metricheck group p=0.082) Hazard ratio for pregnancy following mating start date statistically significantly better in treated group than non-treated group (VV p=0.019, Metricheck p=0.049) – HR greater than 1 for both VV and Metricheck groups (therefore means pregnancy happening faster in treatment group than non-treated groups)
Discussion and conclusion	
What do the main findings/key results mean?	It appears that more animals are pregnant (HR) and are pregnant within 6 weeks of mating start date in treated versus untreated group overall (other parameters like conception to first service and proportion of cows pregnant within 21 weeks

	depended on type of diagnosis)
Are the negative findings discussed? How are the negative findings interpreted?	Yes No mention of study design being a problem, or the fact that they didn't achieve the sample size they calculated they needed
Does the discussion reflect the results?	Mostly, the focus was on the diagnostic testing
Interpretation	
What are the clinical implications of this study? Are the subjects in the study similar to those in the BET/your own?	Pregnancy rates in cows diagnosed as having clinical endometritis by visual vaginoscopy are likely to increase when treated with cephapirin compared with those not treated. Important to note however study limitations, for example the failure to achieve the required sample size. Not all results are applicable to our study population. Also important to note is that the animals within this study are from an "at-risk" population, which have already been selected as they have had a condition making endometritis more likely, so caution should be taken when interpreting these results
General	
Who funded this study?	Not stated, but reports that Intervet Australia Ltd provided the Metricheck devices and product for the trial