Critical appraisal – Randomised controlled trial questions

LeBlanc et al. 2002

Introduction	
Are the aims clearly stated?	Yes
Methods	
Is the study design suitable for the aims?	Yes, RCT approach appropriate for testing treatments
Which population was studied?	Convenience sample of 27 Holstein dairy herds in Ontario and Prince Edward Island, Canada
Were the treatments randomly allocated? If yes, how was the randomisation done?	Yes Computer generated random number list within a herd
Were the groups comparable prior to intervention?	Statistically tested parity group and time of enrollment – no differences. Other parameters (e.g. time to gross involution of uterus) not tested statistically
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 a specific case definition as shown in a

used to make the measurements? (e.g. Glasgow pain score, International Units etc)	previous study to determine if animals had endometritis. No other previously published work was cited here
What outcomes were measured?	Clinical cure (abscence of mucopurulent discharge and cervical diameter <7.5cm) after 14d, pregnancy rate, calving to service interval, first serve pregnancy risk, calving to pregnancy interval, cumulative pregnancy risk, number of inseminations per pregnancy, removal risk for reproductive failure, culling data
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?	Mentioned a p-value for use in constructing the models, but nothing stated in terms of judging whether the final outcome of the model, or other analyses, were significant or not
Was the sample size justified?	No, convenience sample. But then in the discussion they talk about a sample size calculation; it is difficult to determine whether this was post-hoc or not?
Was ethical approval obtained?	Not stated
Are the methods described in enough detail that you could repeat them?	Yes, grossly

Results	
Were the basic data adequately described?	Yes (Table 1)
Do the numbers add up? Are all subjects accounted for?	Yes (Table 3 and text) Mostly – quite a lot missing (although authors did outline the number missing at each examination)
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 No value given in the methods
Were any side effects of the intervention reported if applicable?	No side effects reported, but many animals missing from the second (78 from 223 – 35%) and third (19 from 51 – 37%) examination
What were the main findings/key results?	Crude rates of resolution of clinical signs not significantly different between groups No significant associations between treatment and absolute (univariable?) measure of repro performance (median days to first insemination, first service pregnancy risk, pregnant by 120 DIM, Median days open, Cumulative pregnancy risk, No. of inseminations, Culling risk) In terms of multivariable model, no significant differences for time to first insemination, pregnancy risk at first insemination, no. of inseminations per pregnant cow, culling risk No significant effect of treatment on time to pregnancy relative to control Some differences in terms of cows with a palpable CL and those without – those with had increased pregnancy rates with treatment than without treatment, for those without CL, there was no difference

	Significant effect of treatment on pregnancy rate when treated 27-33DIM (63% increase, P=0.01)
Discussion and conclusion	
What do the main findings/key results mean?	No significant difference between treatment and control at most times post calving, but increase in pregnancy rate when treated between 27-33DIM.
Are the negative findings discussed? How are the negative findings interpreted?	Yes Talk about the study being underpowered, postpartum interval and whether a CL was present or not making a difference. Spontaneous resolution of endometritis a possibility? Say that the literature supports their finding of no difference (but perhaps due to power issues)
Does the discussion reflect the results?	Mostly
Interpretation	
What are the clinical implications of this study? Are the subjects in the study similar to those in the BET/your own?	Treatment is not necessarily better than nothing, may be dependent on time since calving Mostly
General	
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