

Critical appraisal – Randomised controlled trial questions

Culp et al. 2009

Introduction	
Are the aims clearly stated?	<p>Yes</p> <ol style="list-style-type: none"> 1. To describe a technique for laparoscopicovariectomy (LapOVE) in small dogs (<10kg) 2. To report surgical time and complications of this technique compared with open ovariectomy (OOVE) 3. To compare postoperative activity counts measured by accelerometry in small dogs undergoing LapOVE versus dogs undergoing OOVE using the actual activity monitor (AAM)
Methods	
Is the study design suitable for the aims?	Yes
Which population was studied?	20 intact female dogs weighing <10 kg were acquired from an animal welfare society at irregular intervals over 8 months.
Were the treatments randomly allocated? If yes, how was the randomisation done?	<p>Yes</p> <p>Using a block randomization sequence with 2 potential treatment groups</p>
Were the groups comparable prior to intervention?	Not stated
Was the person who administered the interventions blinded?	Not possible
Is it clear what measurements were carried out in the study?	<ul style="list-style-type: none"> • Duration of surgical time • Degree of haemorrhage • Incision length • Activity monitoring using an accelerometer for a) pre surgical 24 hours and b) post-surgery for the first 24 hours (Day 1) and 24-48 hours (Day 2).
Were the correct measurements chosen?	Yes

Do they reflect (or are they strongly related to) the outcome of interest?	Yes
Were previously established validated methods used to make the measurements? (e.g. Glasgow pain score, International Units etc.)	Degree of haemorrhage measured on a new scale but is described in the paper. AAM has been used in previous studies to measure activity
What outcomes were measured?	Surgical variables Activity monitoring
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
Was the sample size justified?	Yes, sample size calculation was done.
Was ethical approval obtained?	Not stated
Are the methods described in enough detail that you could repeat them?	Yes, other than the statistical analysis
Results	
Were the basic data adequately described?	Yes
Do the numbers add up? Are all subjects accounted for?	Yes Yes
Was the statistical significance (p value) stated in the results?	Yes

Is this consistent with the methods? (It should be stated in the sample size or power calculation)	Yes
Were any side effects of the intervention reported if applicable?	Yes
What were the main findings/key results?	<p>Bleeding/ Haemorrhage:</p> <ul style="list-style-type: none"> • 6 dogs in OOVE group with minor bleeding from ovarian or uterine horn pedicle • 3 dogs in LapOVE group had minor bleeding from the mesovarium <p>Incision length:</p> <ul style="list-style-type: none"> • OOVE median incision length 5.2cm (range: 4.5-5.8cm) • LapOVE median incision length 4.2mm (range: 3.8-5.6mm) and for the caudal incision, median 9mm (range 7.2-11.3mm) <p>Surgical time:</p> <ul style="list-style-type: none"> • Median for OOVE 21 mins • Median for LapOVE 30mins • Significantly less in OOVE group (p=0.005) <p>Activity counts change from pre-surgical to post-surgical day 1 and day 2:</p> <ul style="list-style-type: none"> • No significant change for LapOVE group • Significant decrease in activity in OOVE group (p=0.002) <p>Decrease in total activity counts after surgery:</p> <ul style="list-style-type: none"> • LapOVE group 25% decrease (95% confidence interval 11-38%) • OOVE group 62% decrease (95% confidence interval 48-76%)
Discussion and conclusion	
What do the main findings/key results mean?	LapOVE has smaller median incisions than OOVE but significantly longer surgery times. LapOVE patients show no significant change in activity from before to after surgery but OOVE have a significant decrease in activity compared to baseline.
Are the negative findings discussed?	Yes

How are the negative findings interpreted?	Details are presented
Does the discussion reflect the results?	Yes but also discusses in detail the LapOVE technique
Interpretation	
<p>What are the clinical implications of this study?</p> <p>Are the subjects in the study similar to those in the BET/your own?</p>	<p>For dogs under 10kg, the LapOVE approach may lead to greater post-surgical activity levels than OOVE for the first 2 days after surgery. However, the activity levels in this study may also have been affected by the dogs' novel environment. Incisions are also smaller in the LapOVE than OOVE group. However, in this study, surgery time was longer and this needs to be considered.</p> <p>It is possible that the decreased activity in the OOVE group was in part due to those dogs being in greater discomfort. The only post-operative analgesia given to both groups was 2 doses of buprenorphine at 6 hourly intervals. This may not accurately reflect the post-operative analgesia regime given in many veterinary practices.</p> <p>Yes</p>
General	
Who funded this study?	Not stated but work was performed at the School of Veterinary Medicine, University of Pennsylvania.