Optimising design and analysis of acute effect field studies

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INTRODUCTION

Vertebrate risks assessments of a plant protection product (PPP) may indicate an acute risk to wild birds and mammals. This might be driven by (too) conservative assumptions on the exposure side of the equation for the risk evaluation. Therefore it is appropriate to study profoundly the presence of acute effects in the field in order to obtain a correct risk assessment. Here, we highlight three complementary ways to increase the quality of such field studies.

An ideal study design should combine the 'extensive' approach, by using a great area of agricultural fields, with the 'intensive' approach, by using radio-tracking techniques in a control/treatment design. This double approach covers the natural variation in parameter estimates and enables the identification of possible treatment effects.

In the context of a good study design, we also propose an statistical evaluation which can simplify the detectability of effects in comparison to earlier studies.

Fig.1: From left to right: radio-tracking by car, radio-tagged great tit (Parus major), radio-tracking by foot

RESULTS & DISCUSSION

- By means of the radio-tracking method, the survival of a great number of individuals can be monitored.
- The Kaplan-Meier survival curve and the Cox proportional-hazard model provide a helpful estimate of the potential effect of treatment effect on survival. These 2 methods also isolate the effects of treatment from the effects of other covariates, so to assess the outcome of such studies becomes easier.
- Using records from radio telemetry studies it is possible to estimate the number of individuals needed in order to perceive actual treatment effects in the statistical output.
- The minimum sample size to detect a specified effect size with a power of 0.8 using a significance level of 0.1 is highly dependent on the effect size and the standard deviation (SD) of the survival times in the control group and to a lesser extent on the effect scenario.

Tab.1: Sample size and statistical power for different species

Species	N individuals (treatment + control)	Mean power scenario I[1]	SD power scenario I[1]	Mean power scenario II[2]	SD power scenario II[2]	Mean SD in control group
Medium granivorous bird "pigeon"	66	0.84	0.04	0.80	0.05	0.37
small insectivorous/ omnivorous bird "wagtail/lark"	80	0.86	0.11	0.80	0.12	1.08
Small omnivorous mammal "mouse"	132	0.84	0.13	0.80	0.11	2.2

[1] exponential removal of individuals from day 2 after application, [2] linear removal of individuals from day 2 after application

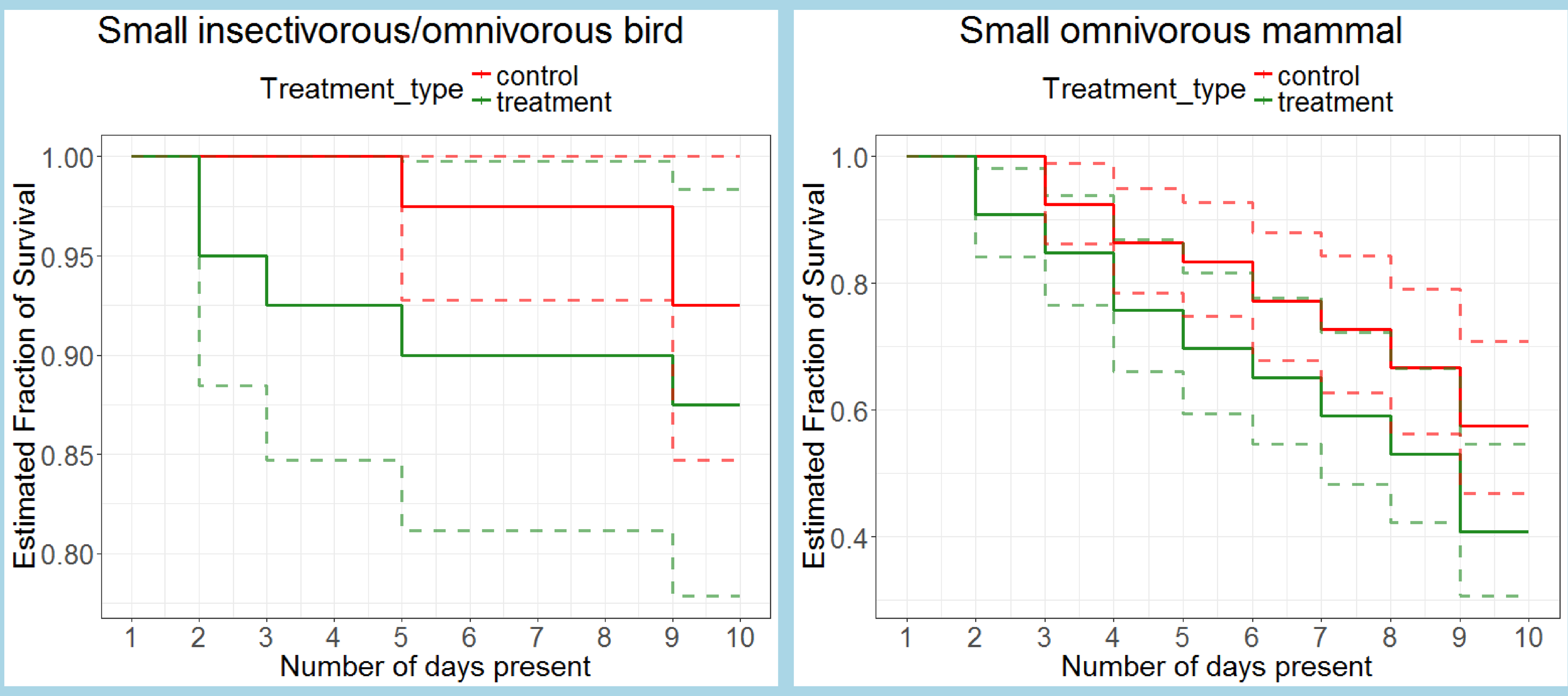

Fig.2: Kaplan Meier survival curve of scenario I for combined datasets of small insectivorous/ omnivorous birds and small omnivorous mammals

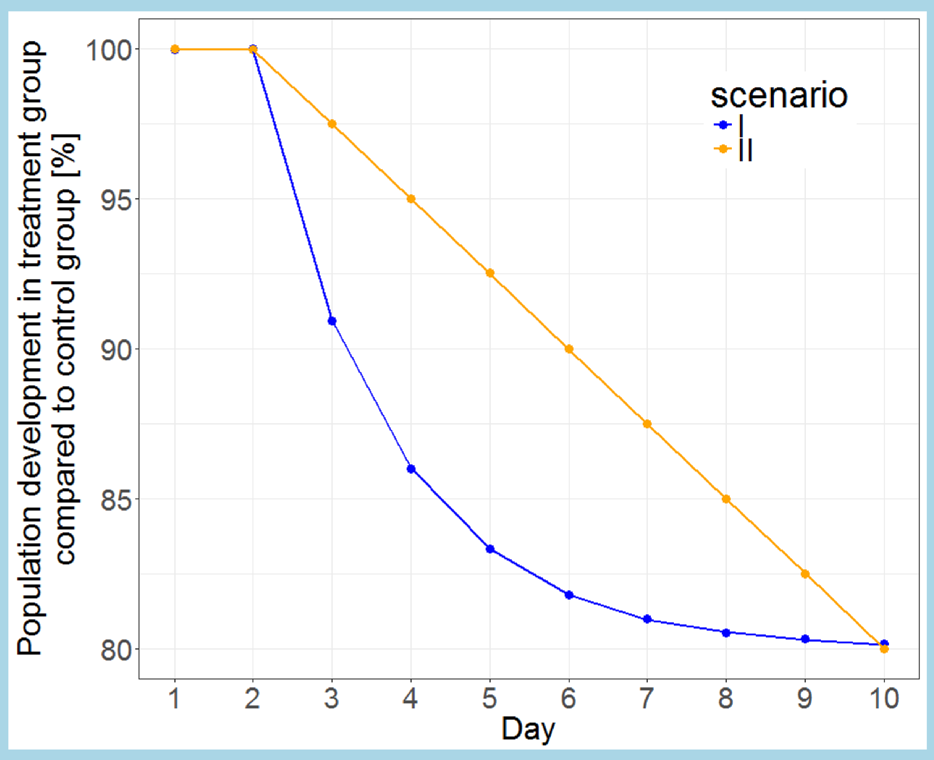

Fig.3: Assumed timing of acute effects after application of a PPP

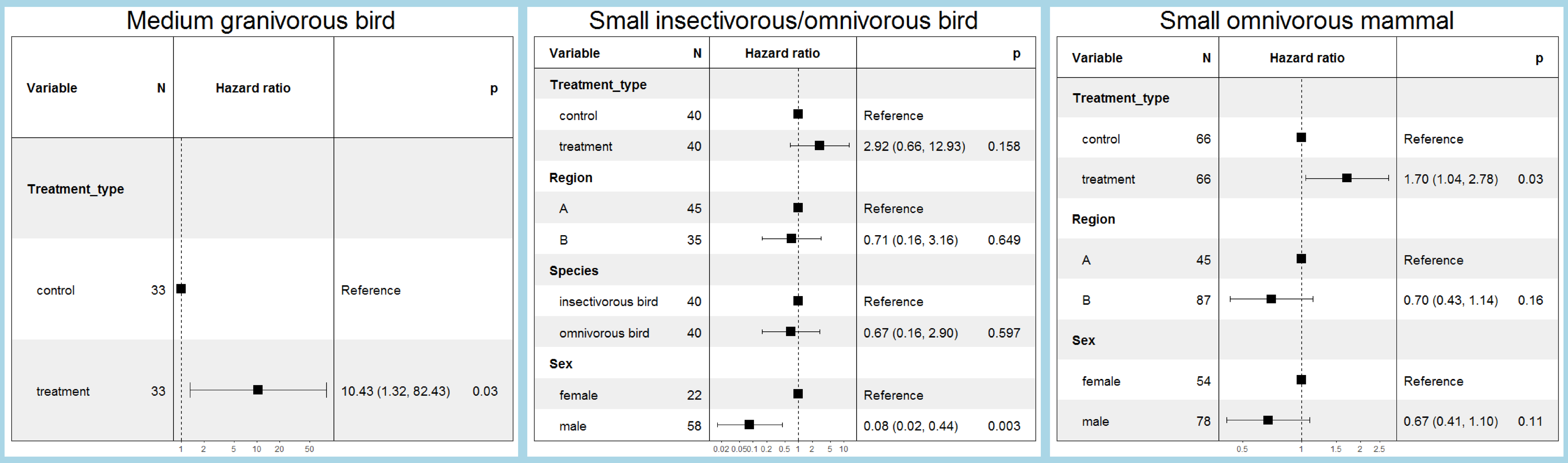

Fig.4: Cox proportional-hazard model of scenario I for combined datasets of medium granivorous birds, small insectivorous/omnivorous birds and small omnivorous mammals

MATERIALS & METHODS

Information about the presence of radio-tagged individuals of different bird and mammal species were collected in the working routine of telemetry studies (2012 – 2017). For each individual the presence during 12 days after tagging was determined. The data were combined based on similarity of species, crop and study season. A fixed number of individuals was sampled from the pooled data with replacement. For half of these individuals the treatment effect scenarios I and II were applied. The resulting datasets were analyzed using the Cox proportional-hazard model, and the model formulas included factor treatment for all species. For the small birds and mammals, region and sex were added; for the small birds the species was added to account for differences between insectivorous and omnivorous birds. The estimation was done 10 times with 100 runs each. The number of times the factor treatment was significant per 100 runs was counted and the mean and SD were calculated. The resulting mean value represents the mean power of the scenario. A level of significance p=0.10 was selected in order to include also results in the analysis which indicate a treatment effect.

Aims were to determine when actual treatment effects in the statistical output could be perceived depending on:
(i) Number of individuals observed **(ii)** Differences in presences between species **(iii)** Differences between action mode of PPP

CONCLUSIONS

- ✓ The **radio-tracking technique** is efficient to monitor the fate of single individuals in a treated population over a long enough time period.
- ✓ The **Cox proportional-hazard model** is the recommended method for the analysis of survival information.
- ✓ The **number** of individuals needed to be monitored depends on, first, the species, and second, the timing of acute effects after application of each specific PPP.
- ✓ This work shows what needs to be considered when planning an acute effect study in order to reduce uncertainties in results interpretation.

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