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Registration of generic alternatives to praziquantel for the control of *Taenia ovis*

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Taenia ovis is a parasite which infects dogs (the definitive host) and sheep and goats (intermediate hosts). It has been the subject of a control programme in New Zealand based largely on the 6-weekly dosing of rural dogs with praziquantel. Since the patent for praziquantel has expired, various generic formulations have become available, including the formulation tested here. It is debatable whether such products should be tested for bioequivalence and biological activity against the target parasite or for bioequivalence only. In this instance, although the drug had been registered on the basis of blood levels of praziquantel achieved, it was felt that a biological test would be beneficial if the generic drug, mixed with other anthelmintics, was to be used on a wide scale to control *Taenia ovis* in New Zealand.

Nine dogs raised and maintained free of cestode infections were orally infected with ten *T. ovis* cysts each, obtained by finely dissecting the musculature of a sheep harbouring an 8-week-old *T. ovis* infection. Dogs were fed frozen and thawed sheep meat and dog biscuits throughout the trial and maintained at Wallaceville Animal Research Centre, Upper Hutt, New Zealand.

Four dogs were treated with arecoline hydrobromide at 3.7 mg/kg 4 weeks after infection and voided one, one, two and seven worms each. The remaining five dogs were weighed and given orally one tablet each of a generic formulation containing 50 mg of praziquantel, 140 mg of pyrantel pamoate and 545 mg of oxantel pamoate in each pill at the recommended dose rate of 5 mg/kg praziquantel. They were treated 1 week later with arecoline hydrobromide at 3.7 mg/kg. No worms were recovered. The dogs were monitored for a further 2 months, and did not produce proglottids.

The results were statistically analysed using an exact test 2 × 2 table. The dosed group differed from the undosed controls ($p < 0.01$). The worms purged are large and easily identified in the purge which gives a definite result (i.e. infected v. not infected). A qualitative test is therefore appropriate.

Gemmell[1] examined the effect of praziquantel on *Echinococcus granulosus*, *Taenia hydatigena* and *T. ovis* in a trial involving 360 dogs. Praziquantel was effective at 1.0 mg/kg in removing all worms from 10 dogs infected with *T. ovis* and 98% effective in removing *E. granulosus*, worms from 60 dogs when used at 5 mg/kg. At 1.25 mg/kg, it was 100% effective in removing all *Taenia hydatigena* worms from ten dogs. Thakur *et al.*[3] dosed groups of ten dogs infected with either mature or immature *E. granulosus*, with praziquantel at 5 mg/kg, and removed all worms.

Dogs vary markedly in their susceptibility to *T. ovis* tapeworm infections[2], but in our experience an infection with ten cysts results in at least one worm establishing in all dogs. In the field, dogs that are infected with *T. ovis* usually harbour between one and three worms and so the number of worms establishing in the dogs used in this experiment is representative of the field situation.

Praziquantel has been shown to be effective at 1.0 mg/kg in removing *T. ovis* infections and 1.25 mg/kg in removing *T. hydatigena* infections[1]. The generic formulation, at 5 mg/kg praziquantel, was shown in this trial to effectively remove *T. ovis* worms from dogs and can be assumed to be effective against *T. hydatigena* also. *Taenia ovis* appears to be more susceptible to praziquantel than *E. granulosus* and so cannot be used as an indicator species for *E. granulosus*.

References

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