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Safety and efficacy of a 100 % dimethicone pediculocide in school-age children

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Efficacy

The data consist of counts of live lice and viable eggs found in 58 subjects at baseline (Day 0) and on Day 1, Day 7, and Day 14 after treatment as shown in Fig. 2. After one day of treatment, 98.30 % of subjects (57 of 58) were free of live lice and 55.20 % (32 of 58) were free of viable eggs. At diagnosis, 55 subjects had viable eggs with three subjects meeting enrollment criteria for three or more live lice. On day 14 of the study, 96.50 % of subjects (55 of 57) were still free of live lice, and 80.70 % (46 of 57) were free of viable eggs. If a child was still found with live lice on day 14, the school nurse notified the guardian to discuss further treatment options, as subjects could not immediately re-enroll in the study. The removal of eggs was facilitated by the viscosity of the product and the lice comb provided, which together eased removal. Of the 58 subjects, 43 received a total of one treat- ment, ten received two treatments and five received three treatments [Table 1]. Subjects received a second or third treatment if lice or viable eggs were confirmed by the school nurse.

Safety

All subjects were monitored by the school nurse at base- line and throughout the study period for adverse effects, including scalp erythema, excoriation, flaking and edema. One adverse event was reported by a parent/guardian dur- ing the study, which was transcribed by the school nurse on the Adverse Event Report form as “Irritation on cheek at time of shampoo application” which occurred “10 min after shampoo was washed off.” The nurse also reported that the irritation lasted 10 min and that no medical atten- tion was needed. There were no reports of significant adverse events during the study. Overall, scalp conditions as assessed by the school nurse improved during the two week study period: 10 subjects (17.5 %) reported mild to moderate scalp erythema on day 1, compared with only one subject (1.7 %) on day 14; 8 subjects (14.3 %) reported mild scalp excoriation on day 1, with none reporting on day 14.

Discussion

This study demonstrates the efficacy and short-term safety for the topical use of 100 % dimethicone for treating pediatric pediculosis. While prior studies have shown efficacy for dimethicone-containing products, to our knowledge this is the first study to document the in vivo safety and efficacy for 100 % dimethicone. Addition- ally, this study design utilized school and daycare set- tings to evaluate children for head lice, which is of practical importance as many children with lice are iden- tified and followed by school nurses. There were several limitations for this study: this was an open label single arm design with no comparison group. Additionally, this study had a short term assessment for adverse events.

Conclusions

A 100 % dimethicone product is a safe and highly effective head lice treatment for children and may serve as a poten- tially less toxic and less resistance prone alternative to pesticide-containing products. Given its safety and efficacy record, dimethicone should be considered as a first-line treatment for pediatric head lice.