



Unpublished Trials in Molluscum Contagiosum: a Case Study in Publication Bias

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Disclosure I have no conflicts of interest

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Interventions for cutaneous molluscum contagiosum (Review)

van der Wouden JC, van der Sande R, van Suijlekom-Smit LWA, Berger M, Butler CC, Koning S

Imiquimod

Cochrane review (2009) included one RCT comparing imiquimod to placebo. N=23. RR for cure 3.67 (95% CI 0.48 to 28)

“well-tolerated and effective” (Theos 2004)

E-mail from Ken Katz (US dermatologist)

“Large scale RCTs comparing imiquimod to placebo, performed by 3M company, have not been published.

I hope that Cochrane review can include these studies.” (July 2013)

Search for trial reports

Several attempts to obtain trial reports by contacting principal investigators. Unsuccessful.

3M sold its dermatology branch. Current proprietor: Meda Pharma

Current proprietor shares unpublished reports

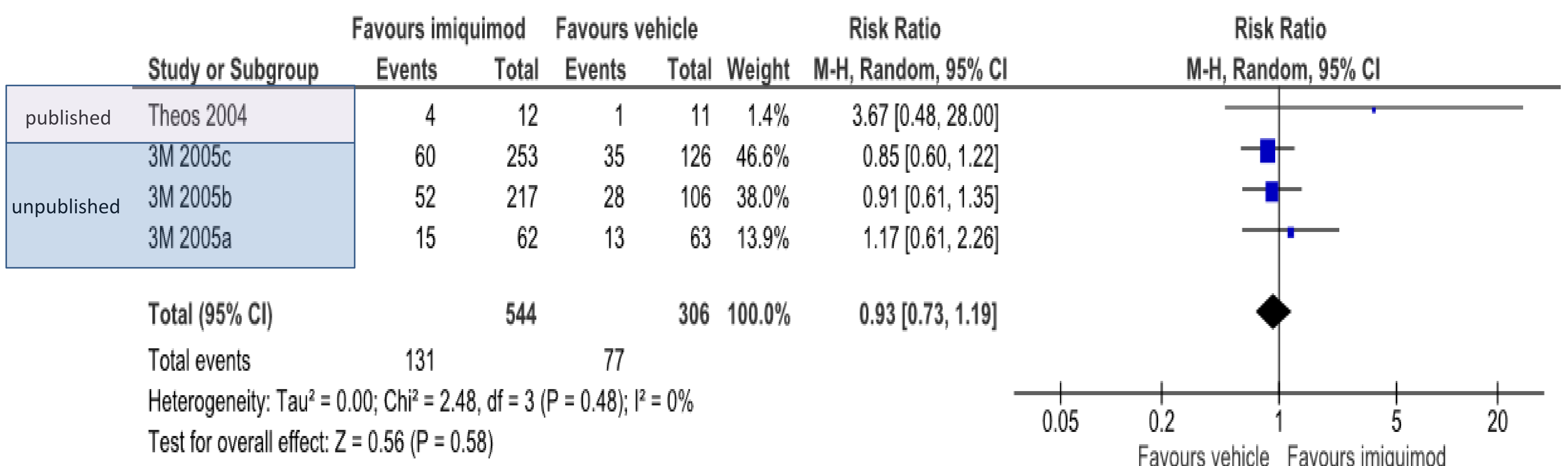
Upon request, Meda Pharma sent us the 3 trial reports. Pooled RR for cure 0.93 (95%CI 0.73 to 1.19) (figure).

Local side effects: any: RR 1.41 (1.13 to 1.7); severe: RR 4.33 (1.16 to 16.19)

Conclusion

Omission of unpublished trials may distort our view of reality. Many children have probably been exposed to painful and ineffective treatment as a result of lack of publication. We should try hard to obtain unpublished trial reports.

Topical imiquimod vs. vehicle (placebo) for molluscum contagiosum Outcome: complete clearance 4 weeks after end of treatment



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Reference: van der Wouden JC, van der Sande R, Kruihof EJ, Sollie A, van Suijlekom-Smit LW, Koning S. Interventions for cutaneous molluscum contagiosum. Cochrane Database Syst Rev 2017 17;5:CD004767.