Propanolol vs Prednisolone for Symptomatic proliferating Infantile Hemangiomas: A Randomized controlled trial.

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Background & Objectives:

- Propanolol is touted as superior to prednisolone for treating infantile hemangiomas.(IH) A randomized clinical trial comparing the outcome, tolerability and effectivity of these two medication for symptomatic IH wasnot reported before.
- Aim is to determine if oral propranolol is more efficacious and better tolerated than prednisolone in treating symptomatic , proliferating IH.
- **Intervention : Treatment with oral propranolol vs prednisolone (2 mg/kg/day) until halted owing to toxic effects or clinical response.**

Methods: Phase 2 , investigator blinded, Multi-institutional, placebo controlled RCT conducted in 3 academic vascular anomalies clinics on 19 of 44 eligible infants aged between 2 weeks to 6 months. Lesions were considered symptomatic if they impaired functions (breathing, eating, vision and hearing) were ulcerated, caused pain or were in cosmetically sensitive areas. Exclusion criteria included proven cardiac anomalies, liver disease, reactive airway diseases, PHACE syndrome. Primary outcome was reduction is size of IH, frequency, site and severity of adverse effects (AE) over 4 months period. Of 44 consecutive eligible patients, 19 were enrolled and randomly assigned to prednisolone(n=8) or propranolol (n=11).

ACADEMIC P.E.A.R.L.S

Pediatric Evidence And Research Learning Snippet

Propanolol versus Prednisolone for symptomatic infantile hemangiomas. Which is safer and effective?

Results:

- Primary outcome showed no difference in lesion size or affected skin at 4 months of therapy : 41% and 1.32mm2 for prednisolone vs 64% and 0.55 mm2 for propranolol (p=0.12 for lesion size and p=0.56 for affected skin area)
- Longitudinal analysis showed a faster response in total lesion outer dimension with prednisolone (p=0.03) but this advantage reduced over longer time.
- The overall frequency of AE(Adverse effects) was similar (44 for prednisolone vs 32 for propranolol , p=0.84) but prednisolone treated patients had more grade 3 severe AEs (11 vs 1) p=0.01 , particularly growth retardation resulting in size and weight below 5th %le.
- Early study withdrawal owing to AEs occurred in 6(75%) of 8 patients in prednisolone group but 0 of 11 propranolol treated group.

Conclusions: Both medications show similar efficacy for reducing the area of symptomatic , proliferating IH Although prednisolone showed a faster response rate, propranolol was better tolerated with significantly fewer severe AEs. Future long term studies necessary to see if propranolol merely hasten the involution process or changes ultimate outcome.

Key message: Propanolol is safer and better tolerated option than prednisolone to treat symptomatic proliferating IH and should be the first line of therapy unless contraindicated .

EXPERT COMMENT

“This landmark phase 2 RCT shows propanol should be preferred over prednisolone for symptomatic IH if no contraindications exist. Prednisolone may show faster response but has high severe AEs than propranolol hence more suitable due to its safety and tolerability although both drugs have similar efficacy .”

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Reference

Bauman NM, McCarter RJ, Guzzetta PC et al. Propanolol vs prednisolone for symptomatic proliferating infantile hemangiomas: a randomized clinical trial. JAMA Otolaryngol Head Neck Surg.2014 Apr; 140(4): 323-30. doi:10.1001/jamaoto.2012.6723