Randomised controlled trials of surgical procedures in children: a cross-sectional study

Background:
Randomised controlled trials represent the best form of evidence when assessing the efficacy of an intervention. Those conducting trials of surgical procedures in children face distinct challenges compared to other surgical and non-surgical specialties. By studying how trials of surgical procedures in children have evolved to overcome these difficulties all specialties can potentially learn valuable lessons.

Objectives:
We aimed to assess the evolution of research methodology and standards in trials of surgical procedures in children over time.

Methods:
We searched the Cochrane Central Register of Controlled Trials (CENTRAL) on the 10/02/2012 and selected randomised controlled trials involving children undergoing surgical procedures published from the years 2000 to 2001 and 2010 to 2011. We assessed the epidemiological and methodological characteristics of these trials and performed logistic regression analyses to determine if there was an association between allocation concealment and key study characteristics.

Results:
We included 112 randomised controlled trials: 39 from 2000 to 2001 and 73 from 2010 to 2011. The number of published trials significantly increased over time, P<0.001. The median sample size per trial was 52 and the mean patient age was 5.3 years, see Table 1. Reporting quality was variable with many trials lacking descriptions of key characteristics that would facilitate their replication. Methodological quality was mixed, with no quality domain significantly improving over time. We could find no association between allocation concealment and key study characteristics.

Conclusions:
Despite the challenges faced, our study demonstrates that randomised trials of surgical procedures in children are feasible and frequently conducted. To aid in the reproducibility of results it is important that trials adequately describe their interventions, settings and participants. This study has important implications for those seeking to conduct their own research and those who are seeking to demonstrate the feasibility of their research proposals.