

Investigating the presence of surgical learning in a randomised trial: the Timing of Primary Surgery for cleft palate (TOPS) trial

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Abstract content

Introduction

When conducting a randomised trial in surgery, it is important to consider surgical learning, where surgeons become more familiar with one, or both, of the interventions during the trial. If present, and unbalanced between groups, learning can compromise trial validity and may require further statistical investigation. We demonstrate an investigation into learning within a surgical trial of cleft palate repair.

Methods/Approach

TOPS was an international, two-arm, parallel-group trial, compared primary surgery, using the Sommerlad technique, for cleft palate delivered at six- or twelve-months of age. Prior to participating, Sommerlad technique experience and routine age for primary surgery varied between centres and surgeons. All participating surgeons therefore underwent pre-trial surgical skill calibration, and the randomisation schedule was balanced on operating surgeon. We apply visual methods and statistical modelling to explore learning for two surgical outcomes: operation time and fistula formation.

Results

26 surgeons operated across 22 centres. As the trial progressed, operation time reduced for surgeons with no pre-trial Sommerlad experience ($n=2$), before reaching a plateau at approximately 30 trial operations, whereas it remained stable for those with prior experience. Fistula rates remained stable regardless of Sommerlad experience. Routine age for primary surgery did not impact selected outcomes.

Discussion

The TOPS trial attempted to reduce learning effects through design, by incorporating skill calibration and balancing randomisation by surgeon, but this was not fully achieved. This statistical investigation illustrates how surgeon skill can be explored using real trial data. These methods can be applied to alleviate specific concerns of surgical learning, or to aid trial interpretation and generalisability.