
Abstract:

BACKGROUND: Infants with congenital heart disease who require central venous lines are at increased risk of thrombosis. Heparin-bonded catheters provide protection from thrombotic events in some children. However, heparin-bonded catheters may not be as effective in infants <=1 year old because of other potential risk factors (smaller vessel size, longer duration of catheter use). No studies have assessed the benefit of heparin-bonded catheters in such specific high-risk populations. The objective of this study was to assess the efficacy of heparin-bonded catheters for preventing thrombosis in infants aged <=1 year with congenital heart disease. Study DESIGN: This study was designed as a randomized, controlled, blinded single-center trial. Infants <=1 year old with congenital heart disease requiring a central venous line for clinical care were randomly assigned to receive either a heparin-bonded catheter or a standard non-heparin-bonded catheter. Catheters were visually indistinguishable. The primary outcome was incidences of both silent and clinically noticeable thrombosis confirmed by ultrasound. Ultrasounds were reviewed by a blinded central adjudication committee. Interim analysis was performed after enrollment of 97 patients. RESULTS: Eighty-seven patients were evaluable (41 of the patients were female). Thrombotic events occurred in 17 (42.5%) of 40 patients in the non-heparin-bonded catheter group and
in 21 (44.7%) of 47 patients in the heparin-bonded catheters group. The study was stopped when the interim analysis showed convincing evidence for no difference between groups over the alternative hypothesis of 50% risk reduction. CONCLUSIONS: Infants with congenital heart disease are at significant risk of both silent and clinically identified thrombosis. There seems to be no advantage in using heparin-bonded catheters in infants $\leq$1 year of age.

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