We found no evidence of benefit or harm associated with miconazole and rifampicin-impregnated PICCs compared with standard PICCs for newborn babies” Gilbert et al (2019).

Abstract:

BACKGROUND: Bloodstream infection is associated with high mortality and serious morbidity in preterm babies. Evidence from clinical trials shows that antimicrobial-impregnated central venous catheters (CVCs) reduce catheter-related bloodstream infection in adults and children receiving intensive care, but there is a paucity of similar evidence for babies receiving neonatal intensive care.

METHODS: This open-label, parallel-group, pragmatic, randomised controlled trial was done in 18 neonatal intensive care units in England. Newborn babies who needed a peripherally inserted CVC (PICC) were allocated randomly (1:1) to receive either a PICC impregnated with miconazole and rifampicin or a standard (non-antimicrobial-impregnated) PICC. Random allocation was done with a web-based program, which was centrally controlled to ensure allocation concealment. Randomisation sequences were computer-generated in random blocks of two and four, and stratified by site. Masking of clinicians to PICC allocation was impractical because rifampicin caused brown staining of the antimicrobial-impregnated PICC. However, participant inclusion in analyses and occurrence of outcome events were determined following an analysis plan that was specified before individuals saw the unblinded data. The primary outcome was the time from random allocation to first microbiologically
confirmed bloodstream or cerebrospinal fluid (CSF) infection between 24 h after randomisation and 48 h after PICC removal or death. We analysed outcome data according to the intention-to-treat principle. We excluded babies for whom a PICC was not inserted from safety analyses, as these analyses were done with groups defined by the PICC used. This trial is registered with ISRCTN, number 81931394.

FINDINGS: Between Aug 12, 2015, and Jan 11, 2017, we randomly assigned 861 babies (754 [88%] born before 32 weeks of gestation) to receive an antimicrobial-impregnated PICC (430 babies) or standard PICC (431 babies). The median time to PICC removal was 8·20 days (IQR 4·77-12·13) in the antimicrobial-impregnated PICC group versus 7·86 days (5·00-12·53) days in the standard PICC group (hazard ratio 1·03, 95% CI 0·89-1·18, p=0·73), with 46 (11%) of 430 babies versus 44 (10%) of 431 babies having a microbiologically confirmed bloodstream or CSF infection. The time from random allocation to first bloodstream or CSF infection was similar between the two groups (HR 1·11, 95% CI 0·73-1·67, p=0·63). Secondary outcomes relating to infection, rifampicin resistance in positive blood or CSF cultures, mortality, clinical outcomes at neonatal unit discharge, and time to PICC removal were similar between the two groups, although rifampicin resistance in positive cultures of PICC tips was higher in the antimicrobial-impregnated PICC group (relative risk 3·51, 95% CI 1·16-10·57, p=0·018). 60 adverse events were reported from 49 (13%) patients in the antimicrobial-impregnated PICC group and 50 events from 45 (10%) babies in the standard PICC group.

INTERPRETATION: We found no evidence of benefit or harm associated with miconazole and rifampicin-impregnated PICCs compared with standard PICCs for newborn babies. Future research should focus on other types of antimicrobial impregnation of PICCs and alternative approaches for preventing infection.

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