

MEDTRONIC REVIEW CLINICAL SUMMARY

Effectiveness of triclosan-coated PDS Plus versus uncoated PDS II sutures for prevention of surgical site infection after abdominal wall closure: the randomised controlled PROUD trial¹

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PRODUCT DISCUSSED: Triclosan-coated sutures

PURPOSE OF THE STUDY

- To obtain reliable data for the effectiveness of triclosan-coated sutures in the prevention of SSIs in abdominal surgery compared with uncoated sutures.

METHODS

1. In total, 1,224 abdominal surgery patients in 24 German hospitals were randomised to either triclosan-coated sutures (607 patients) or uncoated sutures (617 patients).
2. Subsequently, a meta-analysis of 5 RCTs was undertaken.
 - The efficacy of triclosan-coated sutures versus uncoated sutures to reduce SSIs was evaluated in 3,020 abdominal surgery patients.

Study endpoints

- The primary efficacy endpoint was rate of SSI within 30 days of surgery.
- Key secondary endpoints included frequency of wound breakdown, postoperative hospital stay, 30 day mortality and quality of life.

RESULTS

- Among the 1,185 patients in the modified intention-to-treat population, SSI within 30 days was similar between groups (14.8 % for triclosan-coated sutures and 16.1 % for uncoated sutures), as was the proportion of deep infections.
- Secondary endpoints, including frequency of wound breakdown and length of hospital stay, and the rate of serious adverse events were also similar between groups.
- The meta-analysis suggested a significant reduction of SSI with triclosan-coated sutures.
 - 3 single centre trials showed superiority of triclosan-coated sutures, however, the potential sources of bias that could have distorted these results include small sample size, single centre setting, clinical heterogeneity, and varying definitions of SSI.
 - PROUD and another multicentre trial showed no advantage for triclosan-coated sutures. The PROUD trial had the largest sample size of all the trials in the meta-analysis, and shifted the results from superiority of triclosan-coated sutures (before PROUD) towards equality (after PROUD) with coated sutures.

CONCLUSIONS

- In the PROUD study, triclosan-coated sutures were not superior to uncoated sutures in reducing SSI, and therefore cannot be recommended over uncoated sutures.
- PROUD found a SSI rate of 15.4 % in this area (planned midline abdominal surgery), showing that SSIs are an issue in this type of surgery.
- The benefit for triclosan-coated sutures shown in the meta-analysis came only from the single-centre trials and therefore the authors recommend that this conclusion should be reconsidered.
- The PROUD study was a high quality, comprehensive analysis and associated with less bias than the single centre studies.

References:

1. Diener MK, et al. Effectiveness of triclosan-coated PDS Plus versus uncoated PDS II sutures for prevention of surgical site infection after abdominal wall closure: the randomised controlled PROUD trial. *Lancet* 2014;384:142–52.

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