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Clinical paper

Medtronic provides the following synopsis of a clinical publication involving triclosan-coated sutures

Reducing surgical site infections in low-income and middle-income countries (FALCON): a pragmatic, multicentre, stratified, randomised controlled trial

NIHR Global Research Health Unit on Global Surgery, *Lancet (Oct 2021)*

Introduction

Surgical site infection (SSI) is the most common postoperative complication worldwide, representing a major burden for patients and health systems. 2% alcoholic chlorhexidine skin preparation and triclosan-coated sutures for closure of the abdominal fascial sheath are recommended for routine use by WHO, despite only evidence of low-to-moderate quality, high risks of bias, concerns over conflicts of interest, and inconsistent outcome definitions. Furthermore, these guidelines include little data from low- and middle-income countries (LMICs) that are disproportionately affected by higher rates of SSI.

Purpose of the study

The purpose of this study was to undertake a large-scale, pragmatic, multi-county, randomized trial to evaluate the effectiveness of these interventions in LMICs with the aim to establish generalizable, high-quality evidence to inform future global clinical guidelines that are relevant across resource-limited settings.

Methods

- The FALCON study was a pragmatic, multicenter, 2×2 factorial, stratified randomized controlled trial between December 2018 and September 2020 to evaluate interventions to reduce rates of SSI in patients undergoing abdominal surgery. Fifty-four hospitals in seven countries (Benin, Ghana, India, Mexico, Nigeria, Rwanda, and South Africa) participated in the study. Both adult and pediatric patients undergoing abdominal surgery were eligible for inclusion if their operation was predicted to be clean contaminated, or contaminated or dirty, with a planned skin incision of 5 cm or greater.
- Patients were randomized in a 1:1:1:1 ratio to the following allocations:
  1. 2% alcoholic chlorhexidine and non-coated suture.
  2. 2% alcoholic chlorhexidine and triclosan coated suture.
  3. 10% aqueous povidone–iodine and non-coated suture.
  4. 10% aqueous povidone–iodine and triclosan-coated suture. Randomization was stratified by wound contamination (clean-contaminated vs contaminated or dirty) as predicted by the surgeon preoperatively.
- The primary objective of the trial was to assess whether 2% alcoholic chlorhexidine versus 10% povidone–iodine for skin preparation, or triclosan-coated suture versus non-coated suture for fascial closure, reduced SSI up to and at 30 days after surgery for clean-contaminated and contaminated or dirty abdominal wounds.
- The secondary objectives were to assess the effect of the trial interventions on SSI at discharge, reoperation for SSI, mortality, unplanned wound opening, length of index hospital admission, readmission, and return to normal activities, all within 30 days of surgery.

Results

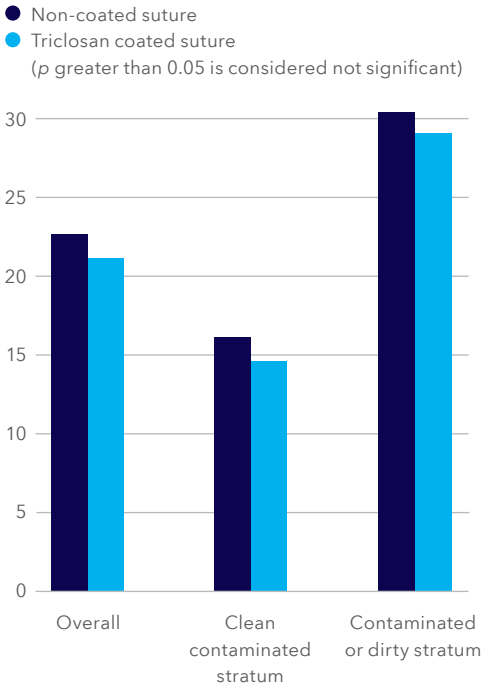
- Note: This summary will focus on suture data. Data regarding skin preparations can be found in the primary manuscript.
- 5788 patients were included in the study: 3091 to the clean-contaminated stratum and 2697 to the contaminated or dirty contaminated stratum. Overall, 14.0% (810/5788) of patients were children, 66.9% (3873/5788) were emergency operations, and 49.0% (2761/5636) of procedures were done through a midline incision.
- The overall SSI rate was 22.0% (1163/5284; clean-contaminated stratum 15.5% [454/2923], and contaminated or dirty stratum 30.0% [709/2361]).
  - In the clean-contaminated stratum, there was no evidence of a difference in the risk of SSI with triclosan-coated sutures versus non-coated sutures (14.7% [215/1459] vs 16.3% [239/1464]; relative risk 0.90, 95% CI 0.77–1.06, p=0.22).
  - **In the contaminated or dirty stratum, there was no evidence of a difference in the risk of SSI between triclosan-coated and non-coated sutures (29.4% [347/1181] vs 30.7% [362/1180]; relative risk 0.98, 95% CI 0.87–1.10, p=0.74).**
- There was no evidence of differences in the secondary outcomes across any strata for either of the interventional comparisons.
- There were no reports of combustions or allergic events. The overall mortality rate was 5.4% (314/5788), which was similar in both trial groups for each of the intervention comparisons.

Conclusion

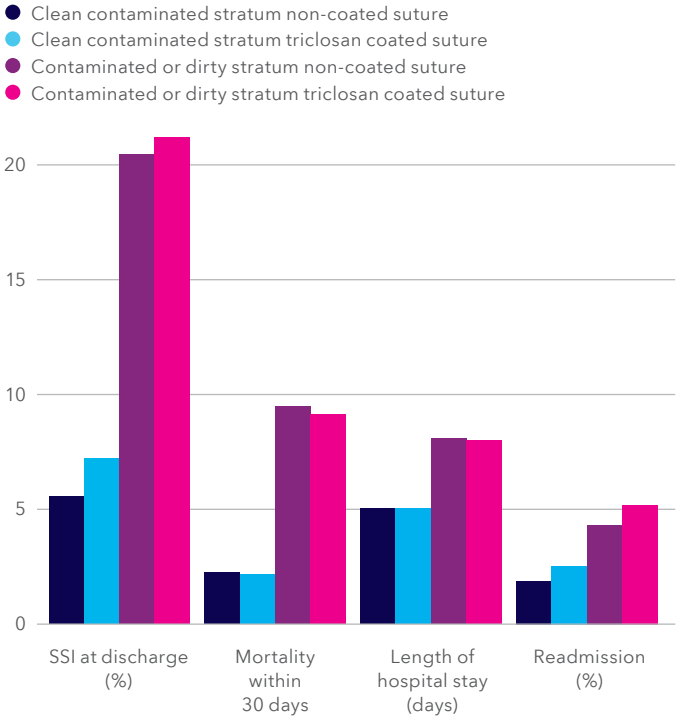
FALCON showed no superiority for the use of triclosan coated sutures over non-coated sutures. The authors state that the guidelines recommend these interventions, either specifically to LMICs or globally, should be revised to prevent unnecessary financial burden.

N=	Clean contaminated stratum	Contaminated or dirty stratum
Triclosan-coated sutures	1550	1345
Non-coated sutures	1541	1352

SSI Rate (%) Fascial Closure



Secondary Outcomes



This concludes the clinical synopsis of this publication

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