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STITCH Trial: Use It With Caution Type Of Study. A Critical Analysis.

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I. Introduction:

The STITCH trial[1] has become a pivotal study in surgical practice, emphasising on the most effective methods for abdominal wall closure. This randomised controlled trial compares small bites to large bites for the fascial closure of midline laparotomy wounds, generating considerable attention within the surgical community. The data indicate a possible decrease in incisional hernia rates associated with the small bites approach, hence questioning conventional practices. Nonetheless, extensive evaluations of the trial's methods, limitations, and greater context of abdominal wall closure are crucial for a comprehensive understanding of its ramifications.

II. Key Findings And Implications

The STITCH trial revealed a reduced occurrence of incisional hernia in individuals undergoing small bites closure versus large bites closure. If reproduced in future trials, this finding could potentially result in a paradigm shift in abdominal wall closure techniques. Nevertheless, numerous things must be evaluated prior to the full implementation of the small bites' strategy.

III. Methodological Considerations

- **Study Design and Power:** While the STITCH trial was a well-designed, randomised, perspective, multicentric, double blind trial, the relatively small sample size and the potential for selection bias might limit the generalizability of its findings.
- **Suture Material and Technique:** The selection of suture material and the particular technique employed for closure can affect outcomes. The STITCH trial employed a standardised methodology; however, changes in practice may influence outcomes.
- **Patient Characteristics:** The trial concentrated on elective abdominal surgery, and the results may not be relevant to emergency surgery or individuals with specific risk factors, lacks demographic diversity.

IV. Weakness And Limitations:

1. **Different Materials And Needle Sizes:** The STICH trial did not standardise suture materials and needle sizes to eliminate bias, preventing us from discussing suture material versus method.
2. **Mixed Set Of Data:** The dataset comprises both clean and contaminated laparotomies, with higher rates of mortality and relaparotomy observed.
3. **Lack Of Prolonged Period Observation:** This trial did not demonstrate the hernia rate that may occur over an extended period; a one-year follow-up is insufficient for assessing incisional hernia formation.
4. **Omission Of Suture Comparison:** The trial failed to compare interrupted versus running sutures.
5. **Cost-Effectiveness:** The potential cost implications of the small bites' technique, including increased suture usage and longer operating time, needs to be evaluated.
6. **Risk of Bias (ROB):** An element of bias will always exist; a surgeon employing a small stitch may strive for improved performance.
7. **Imaging Disparity During Follow-Up:** The benchmark radiological follow-up typically entails a CT scan; however, this was not applied in this instance. Not all patients underwent CT scanning; many received ultrasound scans, some were subjected to CT scans, and others only had home visits.
8. **Suture Length To Wound Length Ratio Insufficiency:** The STITCH trial indicates that roughly 10% of patients in the short-stitch cohort and roughly 3% of patients in the long-stitch cohort exhibited an inadequate ratio of suture length to wound length.

9. **Varying Rates Of Incisional Hernia:** The rates of incisional hernia among participating institutions exhibited significant variation, ranging from 0% to 25%. The results of the surgery vary significantly among the institutions and surgeons involved in the STITCH trial.
10. **Excessive Incisional Hernia Reoccurrence Rate:** The incidence of incisional hernia at the one-year follow-up in the large bites cohort is too much for elective procedures.
11. **Risk Of Surgical Site Infections:** Patients with a surgical site infection exhibited an almost twofold increase in risk of developing an incisional hernia relative to those without the infection.
12. **Generalisability:** The trial was conducted in the Netherlands, and the findings may not be directly applicable to other populations or healthcare systems.

V. Discussion:

The STITCH trial presented a novel subject at all general surgery conferences. We would contend that it introduced further confusion to the surgical faculty general and to trainees specifically. We found it intriguing, and the findings appeared remarkable first, encompassing subspecialties such as vascular, gynaecology, upper gastrointestinal, and lower gastrointestinal. We believe the trial has flaws at various levels like designs, and the conclusions drawn by it are invalid.

The comparison of two different suture materials and needle is inappropriate and should have been standardised to eliminate bias. This could prevent us to comment on the technique vs suture material itself.

The data is a mixed set of clean laparotomies with contaminated ones, mortality and relaparotomy rates were high. These rates are not representative of subspecialities like gynaecology or cancer surgery.

The hernia rate that may happen over a prolonged period was not shown by this trial; a one year follow up is too short for incisional hernia formation as studies have shown more than 60% detection of incisional hernia at 3 years, and it is time dependent since we may find more at 5 years or 10 years. There was also no subgroup analysis; the trial ended in 2012 and was published in 2015, there should have been 3 years follow up.

The technique did not compare interrupted to running sutures. Results from a meta-analysis of randomised controlled trials using various suture materials showed an advantage in using running sutures,[2] whereas a large multicentre randomised controlled trial[3] did not show a difference between the two techniques. There will be always an element of bias as surgeon with small stitch would be trying to perform better. The Hawthorn effect cannot be ruled out. The risk of bias in selection of reported results has been shown in other studies[4].

The radiological follow up is generally considered to be a CT scan, but it was not the case here. Not all the patients were scanned; most of them got ultrasound scans, some got CT scan, some got home visits only. Considering ultrasonography is an operator-dependent investigation, about three-quarters of patients received radiological imaging during follow-up. The trial results need careful consideration in view of its limited follow up.

The STITCH trial appears to be structured as a randomised controlled trial, wherein wounds were closed with an insufficient ratio of suture length to wound length in 9.8% of patients in the short-stitch cohort and 2.9% of patients in the long-stitch cohort. As the stitch length decreases, attaining an acceptable suture length to wound length ratio may become increasingly challenging[5].

In a multicentre randomised controlled study, the rates of incisional hernia across participating institutions varied significantly, ranging from 0% to 25%. If the results of the surgery differ significantly among the institutions and surgeons in the STITCH trial, the use of running sutures with a small tissue bite may lack broad generalisability[6].

Nonetheless, the 21% occurrence of incisional hernia at the one-year follow-up in the large bites cohort is too large for elective procedures[7]. According to a previous systematic review, the prevalence of incisional hernias following midline incision was 12.8% (range 0–35.6%) over a mean observation duration of 23.7 months.

The STITCH trial investigators highlighted the absence of evidence-based guidelines for emergency laparotomies, as these procedures are frequently contaminated, hence increasing the risk of surgical site infections[8]. Patients with a surgical site infection were found to be 1.9 times more predisposed to developing an incisional hernia compared to those without such an infection[9].

The STITCH trial cannot be accepted as an answer for prevention of incisional hernias but might be accepted as a new technique of abdominal wall closure albeit with caution as the STITCH trial fails to address this issue also. To provide surgeons with more accurate information regarding the most effective methods for closing midline wounds, it is necessary to conduct a study with a design that removes as many other variables as humanly possible

Consequently, despite the current research being limited to elective surgery, we are apprehensive regarding the appropriate level of matching between the two study groups concerning unexplained underlying risk factors for surgical site infection or incisional hernia, including:

1. The duration of the procedure,

2. The volume of blood loss,
3. The classification of surgery as clean or contaminated, and
4. The presence or absence of a stoma.

There was disparity in the type of suture (material) and size of (thinner) needles while the length of suture needed further research. Questions are still lurking around like safety concerns with large bite's technique employing small sutures sizes, or the small bites technique utilising large sutures. Additional research is required to determine if smaller bites or finer needles and suture materials reduce incisional hernias in the small bite's cohort.

VI. Conclusion

The STITCH trial provides valuable insights into the potential benefits of small bites closure for abdominal wall incisions. However, further research is needed to confirm these findings, assess their generalisability, and evaluate the long-term implications. A multi-faceted approach that considers patient-specific factors, surgical technique, and postoperative care is likely to be the most effective in reducing the risk of incisional hernia.

Additional Considerations:

- Meta-Analyses: Future meta-analyses incorporating the STITCH trial and other relevant studies can provide a more comprehensive understanding of the relationship between closure technique and incisional hernia risk.
- Subgroup Analyses: Analysing the effects of small bites closure in specific subgroups of patients, such as those with obesity or diabetes, could help to identify populations that may benefit most from this technique.
- Cost-Benefit Analysis: A thorough cost-benefit analysis should consider not only the direct costs of suture materials and operating time but also the indirect costs associated with incisional hernia, such as reoperations and patient morbidity.

In conclusion, while the STITCH trial offers promising evidence for the potential benefits of small bites closure for abdominal wall incisions, further research is necessary to establish its definitive role in clinical practice. A comprehensive approach that considers the broader context of abdominal wall closure and addresses the limitations of the current evidence base is essential for optimizing patient outcomes.

Conflict of interest: None

Reference:

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