TITLE: Antibacterial Sutures for Wound Closure After Surgery: Clinical Effectiveness and Guidelines for Use

DATE: 11 August 2010

CONTEXT AND POLICY ISSUES:

Surgical site infections (SSIs) occur when pathogenic organisms proliferate in surgical wounds, resulting in local signs of infection such as heat, redness, pain and swelling. Serious SSIs can progress from local to systemic infection, causing fever and increased white blood count. Surgical site infections can impede wound healing, cause separation of the wound edges (dehiscence) and increase the risk of abscess in deeper wound tissues. As such, SSIs are associated with increased mortality, longer length of hospital stay, greater risk of readmission and higher health care costs.

Surgical site infections are the second most common adverse event experienced by hospitalized patients, but the risk of SSI is dependent on a number of factors. The rate of SSI is related to the surgical site, occurring in less than 2% of clean (the operative procedure does not enter into a normally colonized part of the body) sites and exceeding 10% in sites that are considered contaminated (gross contamination is present without infection) or dirty (active infection is already present). Other factors that affect the risk of SSI include contamination of the wound at closure, pathogenicity and number of microorganisms at the surgical site, the host’s immune response, and the presence of microorganisms on instruments or in the operating theatre.

Sutures can be a source of surgical wound contamination due to bacterial adherence and colonization. Sutures impregnated or coated with antibacterial agents have been developed in an attempt to reduce bacterial adherence and colonization of suture materials. Vicryl Plus®, a suture made from polyglactin 910 (an absorbable suture material) coated with the antiseptic agent triclosan, is an example of one such product.

This report is an update to a previous rapid review of antibacterial sutures for wound closure following surgery that was completed in September 2008 and will review the evidence of clinical
effectiveness, safety and guidelines for use of antibacterial sutures for preventing surgical site infections that has been published more recently.

RESEARCH QUESTIONS:

1. What is the evidence of clinical effectiveness of antibacterial sutures for the prevention of surgical site infections?

2. What is the evidence of long-term adverse effects of using antibacterial sutures including increased bacterial resistance?

3. What are the guidelines for the using antibacterial sutures for wound closure?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID’s Medline, the Cochrane Library (Issue 7, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between August 1, 2008 and July 15, 2010. No filters were applied to limit the retrieval by study type.

SUMMARY OF FINDINGS:

The literature search identified two randomized controlled trials (RCTs)\(^4,6\) and one evidence-based guideline which included a systematic review of the literature\(^1\) that met the selection criteria for this rapid review. It is likely that one of the included trials\(^6\) is a duplicate publication of an RCT included in the previous rapid review.\(^5\) Characteristics of the included RCTs can be found in Appendix 1.

Randomized controlled trials

A 2009 RCT\(^4\) was conducted to assess the efficacy of an antibacterial suture (polyglactin 910 coated with triclosan) compared to uncoated polyglactin 910 sutures in reducing rates of SSI in patients undergoing appendectomy (Appendix 1). Surgeons and assistants were blinded to suture type as similarity in appearance made the two products indistinguishable. Baseline patient characteristics did not differ between treatment arms. The authors did not describe how SSI was defined for the purpose of outcome assessment. The rate of SSI was not statistically significantly different between the two treatment groups, nor was the complication rate after one year (Table 1). The authors concluded that polyglactin 910 coated with triclosan was safe in surgical practice, with a comparable outcome to polyglactin 910 but that more study was needed to confirm this. Limitations to this study include lack of clarity in reporting of the timing and manner in which outcomes were assessed. Further, potential issues with generalizability of the study results could arise from the use of second-year residents to perform the surgery, local infection and resistance patterns in Thailand differing from Canada, differences in surgical protocols, co-interventions and surgical techniques. As well, it is not clear that the results would be generalizable to other surgical sites.
A 2009 pilot study assessed the effect of triclosan coated sutures (polyglactin 910 coated with triclosan) on wound healing relative to standard sutures (polyglactin 910) in patients undergoing surgery for breast hypertrophy (Appendix 1). Each patient served as her own control and was randomly assigned to suturing of the surgical incision with polyglactin 910 coated with triclosan in the right or left breast and polyglactin 910 in the other. Surgeons were blinded to the suture material as they were identical in appearance. The rate of wound dehiscence was higher with polyglactin 910 coated with triclosan than polyglactin 910, three weeks after surgery (Table 1). The authors concluded that their findings, when combined with a lack of evidence supporting the use of sutures coated with triclosan, suggested additional research was needed prior to widespread adoption of this product. Limitations to this study include the lack of data on SSI and other adverse event rates. Further, it is not clear if a similar outcome would be expected with surgeries involving other surgical sites.

Table 1: Outcome assessment and study results

<table>
<thead>
<tr>
<th>Study Authors, Year</th>
<th>Outcome Measures</th>
<th>Timing of Outcome Assessment</th>
<th>Results</th>
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<tbody>
<tr>
<td>Mingmalairak et al., 2009</td>
<td>Rate of surgical site infection</td>
<td>Day 1, 3, 7, 14, 30 and 6 months and 12 months post-surgery</td>
<td>Rate of Surgical Site Infection* polyglactin 910 coated with triclosan: 10% polyglactin 910: 5% p=0.727 Complication rate related to sutures (1 year): No complications in either group (allergies or adverse effects)</td>
</tr>
<tr>
<td>Deliaert et al., 2009</td>
<td>Dehiscence - defined as spontaneous disruption of the wound with or without infection occurring within three weeks of surgery</td>
<td>One, two and four weeks following surgery</td>
<td>Rate of Wound Dehiscence (Day 21): polyglactin 910 coated with triclosan: 61.5% polyglactin 910: 27% p=0.023</td>
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</table>

* Timing of outcome assessment not reported

Guidelines and recommendations

The scope of a 2008 guideline and recommendation for the prevention and treatment of surgical site infections from the National Institute of Health and Clinical Excellence (NICE) included an assessment of the type of closure method (including suture type) that should be used to reduce the risk of SSI. A systematic review of the literature was performed to synthesize the evidence base for the guideline. A multi-professional and lay-person working group lead the development process in accordance with NICE’s standard methodology, which included systematic searches, retrieval of evidence, successive drafting of the guidelines, review and expert consultation.

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Stakeholders were also consulted during guideline formulation. Recommendation statements were made based upon informal consensus. Evidence statements included the level of evidence identified from the systematic review.

One study\(^5\) was identified in the systematic review that involved a comparison between triclosan-coated sutures and traditional polyglactin 910 sutures.\(^7\) The criteria and methodology for study selection were not outlined in the report. This study was summarized in the previous CADTH rapid review of anti-bacterial sutures and included 135 pediatric general surgery patients.\(^5\) Ford et al.\(^5\) found that the odds ratio (OR) for SSI was 2.49 (95% CI: 0.12; 52.89), indicating a higher risk of SSI in the triclosan-coated suture group. Two SSI infections occurred in the triclosan-coated suture group compared to zero in the traditional polyglactin 910 suture group. Based on this study, the guidelines state that there was insufficient evidence to determine whether the rate of SSI differed between triclosan-coated or traditional non-coated polyglactin 910 sutures. This recommendation was given a level of evidence rating of 1\(−\). A rating of 1\(−\) was given to any recommendation that was based upon either meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.

**Limitations**

The literature search conducted for this rapid review is limited as described in the methods section. As such there is a possibility that potentially relevant literature might not be identified.

Since the previous rapid review of the clinical effectiveness of antibacterial sutures for the prevention of SSI, two RCTs have been published, one in appendectomy and one in surgery to correct breast hypertrophy. While the study in appendectomy\(^4\) followed patients for one year, it is not clear how outcomes were assessed at that point, so evidence of long-term safety remains limited. The second study\(^6\) appeared to be a duplicate publication included in the previous rapid review, so might not add to the body of literature on this topic.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

The included studies suggest no clear benefit in terms of reduction in SSIs and potential harm (wound dehiscence) associated with the use of triclosan-coated polyglactin 910 sutures compared to regular polyglactin 910 sutures. While results from one RCT suggested no adverse effects one year following surgery, this study involved a single surgical intervention (appendectomy) and was conducted in one centre, so the generalizability could be limited. One evidence-based guideline stated that evidence was insufficient to determine if the rate of SSI was lower with triclosan-coated sutures. Given the lack of efficacy evidence and the potential for harm, more research is needed prior to wide-spread adoption of this technology as a means of reducing SSIs and their associated complications.

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REFERENCES:


5. Ho C, Spry C. Antibacterial sutures for wound closure after surgery: a review of the clinical effectiveness and long-term adverse effects [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008 Sep 17. Available from: http://www.cadth.ca/media/pdf/I0029_antibacterial_sutures_wound_closures_after_surgery_htis-2.pdf


### APPENDIX 1: Characteristics of included randomized controlled trials

<table>
<thead>
<tr>
<th>Study Authors, Year</th>
<th>Study Design</th>
<th>Population</th>
<th>Intervention Comparator and Co-Intervention</th>
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</thead>
</table>
| Mingmalairak et al., 2009<sup>4</sup> Funded by the university Thailand | Double-blind, randomized, controlled, single centre | **Description**
Patients undergoing appendectomy at a university hospital in Thailand | **Intervention**
polyglactin 910 coated with triclosan (Vicryl Plus®) n=50 |
|                     |             | **Inclusion criteria** | | **Comparator**
polyglactin 910 (Vicryl) n=50 |
|                     |             | - Aged 15-60 years | | **Co-Intervention**
Prophylactic gentamicin 240 mg and metronidazole 500 mg IV 30-60 minutes before operation n=100 (All participants) |
|                     |             | - Appendicitis was diagnosed intra-operatively | | |
|                     |             | - Acute or ruptured appendix. | | |
| Deliaert et al., 2009<sup>6</sup> Funding not reported The Netherlands | Double-blind, randomized, controlled, single centre | **Description**
Patients undergoing surgery for breast hypertrophy at a medical centre in the Netherlands | **Intervention**
polyglactin 910 coated with triclosan (Vicryl Plus®) n=26 breasts |
|                     |             | **Inclusion criteria** | | **Comparator**
polyglactin 910 (Vicryl) n=26 breasts |
|                     |             | - Female | | **Co-Intervention**
No use of prophylactic antibiotics |
<p>|                     |             | - Aged 16-65 years | | |
|                     |             | - Bilateral breast size &gt; cup DD | | |
|                     |             | - Clinical complaints such as intertrigo, head, neck shoulder complaints. | | |
|                     |             | <strong>Exclusion criteria</strong> | | |
|                     |             | - Diabetes | | |
|                     |             | - Immune system impairment | | |
|                     |             | - Malignancy | | |
|                     |             | - History of allergy | | |
|                     |             | - Pregnancy | | |</p>
<table>
<thead>
<tr>
<th></th>
<th>degenerative diseases</th>
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<td>IV: Intravenous</td>
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