

# Preliminary Report

## Efficacy of Antimicrobial Coating Suture Coated Polyglactin 910 with Tricosan (Vicryl Plus) Compared with Polyglactin 910 (Vicryl) in Reduced Surgical Site Infection of Appendicitis, Double Blind Randomized Control Trial, Preliminary Safety Report

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**Objective:** To evaluate the efficacy and safety of new antibacterial suture (Vicryl Plus) compared with a traditional braided suture (Vicryl) in a clinical study. The primary goal was to study effectiveness on reduced surgical site infection in an appendectomy operation. The authors' secondary goal was to analyze the safety and physical properties of Vicryl plus.

**Material and Method:** This was a prospective, randomized, controlled, double blind, comparative, single-center study. After appendectomy was done, the patients were randomized in two groups: Vicryl Plus and Vicryl to selected suture for suturing the abdominal sheath. The surgical site infection was evaluated for 30 days, 6 months, and 1 year. The surgeons and attending doctor were blind to the type of suture. This is the primary report of the first 100 patients.

**Results:** There was no difference in demographic and preoperative clinical in both groups. Although there was no statistical difference in the surgical site infection of Vicryl and Vicryl Plus (8 and 10%,  $p = 0.05$ ), one case of deep surgical site infection was detected in the Vicryl group. No complications and no difference in related suture materials were detected.

**Conclusion:** Coated polyglactin 910 with tricosan (Vicryl Plus) is safe and satisfactory in surgical practice. Surgical site infection of appendectomy seemed too to be comparable between coated polyglactin 910 with tricosan (Vicryl Plus) and traditional polyglactin 910 (Vicryl) group.

**Keywords:** Appendicitis, Appendectomy, Polyglactin 910, Surgical wound infection, Tricosan

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Most surgical site infections (SSI) are related to suture. The superficial and deep reached 90% of SSI<sup>(1)</sup>. The surgical infection contributes to financial morbidity. Although efficacy against surgical infection: a strict aseptic technique, antibiotic coverage (when indicated), and an adequate surgical technique were applied, Infection rate remained high.

Recently a new antimicrobial suture has been introduced in the market: Polyglactin 910 coated with

tricosan (Vicryl Plus). Tricosan is a broad spectrum antiseptic that has been widely used in humans for over 30 years<sup>(1)</sup>. There was no evidence of carcinogenic potential, genotoxicity, and skin sensitization potential in 2 years animal model studies<sup>(2)</sup>. *In vitro* study, showed efficacy against *S. aureus*, *S. epidermidis*, MRSA, MRSE, Vancomycin resistant *Enterococcus fecalis*, *Pseudomonas aeruginosa*, *Corybacterium spp.* and *E. coli*<sup>(1,3,4)</sup>. Many studies have reported clinical use of this suture in animal models. The human clinical study had only one report from Ford HR, et al<sup>(5)</sup>. They did not study efficacy of surgical infection, although they reported physical

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properties, intra-operative handling, and wound healing characteristics in pediatric operations.

An appendectomy is the most common operation in Thailand. The surgical infection is the most frequent complication. A complication on a wound requires 5 additional days of care at a cost of approximately \$ 400<sup>(6)</sup>. Many techniques were developed to decrease these complications but are still ineffective<sup>(7,8)</sup>.

In the present study, the authors have evaluated the efficacy of coated polyglactin 910 with tricosan (Vicryl Plus) in reducing the surgical site infection of appendectomy compare with traditional polyglactin 910 (Vicryl). To the knowledge of the authors, this is the first clinical practice study in potential utility of this new tool, the antimicrobial suture.

#### Material and Method

The authors designed a prospective, randomized, controlled, double blind, comparative, single-center study to evaluate the efficacy of coated polyglactin 910 with tricosan (Vicryl Plus) in reducing the surgical site infection of appendectomy when compared with traditional polyglactin 910 (Vicryl). The authors' secondary goal was to analyze the safety and physical properties of Vicryl plus. The present study was undertaken at Thammasat University Hospital, Pathumthani, Thailand. Inclusion criteria were patients aged 15-60 years-old, both sexes, appendicitis was diagnosed by intra-operative who operated with right lower quadrant incision and included both acute and ruptured appendix. Exclusion criteria were patient with diabetes, immunocompromised host, HIV, on immunosuppressive drug, malignancy, missed diagnosis intra-operative, history of allergy to this substance, or pregnancy. The authors set the discontinuation criteria infection rate > 10% in Vicryl Plus group or > 2 times compared with the Vicryl group, mechanical problem in Vicryl Plus suture such as strength, knot tight, and anaphylactic allergy

The patients signed a consent form when appendicitis was diagnosed. Prophylactic antibiotic, gentamicin 240 mg and metronidazole 500 mg, were given intravenously 30-60 minutes before operation. Suture was random by random table<sup>(9)</sup> and packed in order. Both sutures were similar in physical properties. Surgeons and collected assistant were blind to the type of suture. When the appendectomy was done, the suture was selected to close the abdominal sheath. The appendectomy was done with standard technique.

The physical properties were determined by a surgeon. The surgical infection and safety data were determined at post-operative day 1,3,7,14 and 30 days and 6 and 12 months.

The sample size was calculated from two independent samples by

$$n/\text{group} = (Z_{\alpha/2}\sqrt{2P_cQ_c} + Z_{\beta}\sqrt{P_tQ_t + P_cQ_c})^2 / (P_t - P_c)^2$$

The sample size in each group was 672 patients at 95% confident interval. The authors reported the first 100 patients about safety and physical properties to proceed with the complete study.

All data were collected, coded, and analyzed using SPSS software version 15 for Windows. Continuous variables were compared with the independent Student's t-test, whereas the Chi-square test (or Fisher's Exact Test when appropriate) was used to compare proportions between groups. The p-value < 0.05 was considered statistically significant. The present study was accepted by Ethics Committee, Faculty of Medicine, Thammasat University.

#### Results

The authors studied 100 patients between August 2006 and March 2007. All patients completed the study. The authors found surgical site infection (SSI) in 8% of patients undergoing appendectomy. The rate of surgical wound infection was higher in men than in women with the ratio of 3:2. Most patients had symptoms approximately a day before coming to the hospital (Table 1). The common presenting signs and symptoms were abdominal pain with migration of pain (75%), anorexia (86%), and nausea and vomiting (75%). The average body temperature of patients was 37.5°C. The physical examination showed right lower quadrant tenderness but rebound tenderness was found in only 76% of these patients. The laboratory result showed that the average white blood cell count was 15,755 cells/mm<sup>3</sup> and most were neutrophils (82%) (Table 2).

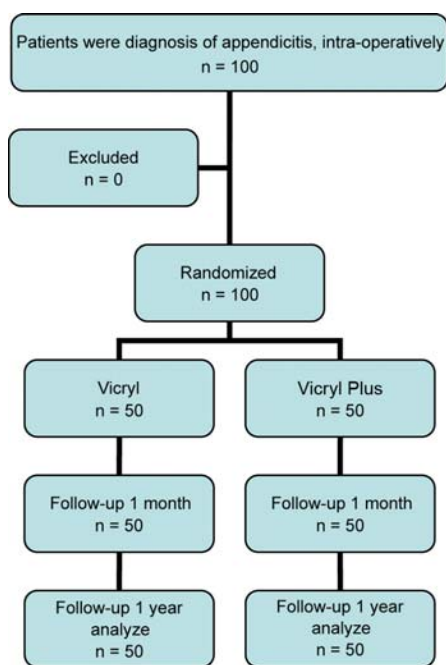
Appendectomy was performed mainly by second-year resident physicians. The average preoperative time and operative time were 290 and 43 minutes, respectively. Appendectomy was done via the grid-iron incision (86%). Cases of appendicitis were divided into uncomplicated (76%), which were acute (24%) and suppurative (52%) and complicated appendicitis (24%), which were gangrene (8%) and ruptured (16%). Appendicitis was found at retrocecal (43%) and pelvis (36%) positions (Table 3).

There were no statistically significant differences (p = 0.05) in demographic characteristic,

preoperative information and operative information between the two groups of patients. The surgical wound infection rates were 8% and 10% in patients using Vicryl and Vicryl Plus sutures, respectively. These rates showed no statistically significant differences. The infection at surgical wounds mostly was superficial SSI. In a group of patients using Vicryl Plus, a case of deep SSI infected with *Pseudomonas aeruginosa* and a case of superficial SSI with *Staphylococcus aureus* were identified. There was no statistically significant difference ( $p = 0.05$ ) in hospitalization time (Table 4) and no medical complication during the present study.

In contrast, patients with infection had significantly longer hospital stay than the uninfected group (7.4 days compared to 3.6 days). Infections were found more frequently in patients with a ruptured appendicitis. Patients with infection were slightly older, had slightly higher body temperature and had slightly higher white blood cell count compared to uninfected patients; however, these parameters were not significantly different ( $p = 0.05$ ) (Table 5).

The surgeon could not separate both types of sutures, and there was no difference in handling suture. No complication related suture was identified after follow-up of 1 year.



**Fig. 1** The diagram showing the flow of participants through each stage of a randomized trial

**Table 1.** Epidemiology of the two groups

	Vicryl	Vicryl Plus	p-value
Sex M : F	35:15	26:24	0.065
Age (year)	29.8	29.1	0.713
Height (cm)	164.0	161.5	0.039
Weight (kg)	59.53	59.73	0.752

**Table 2.** Clinical data of the two groups

	Vicryl	Vicryl Plus	p-value
Migration of pain (%)	74	76	0.817
Anorexia (%)	82	90	0.249
Nausea vomiting (%)	78	72	0.488
Temp (°C)	37.6	37.5	0.617
Rebound (%)	78	74	0.640
WBC (cell/mm <sup>3</sup> )	15,062	16,564	0.036
PMN (%)	81	80	0.446

**Table 3.** Operative data of the two groups

	Vicryl	Vicryl Plus	p-value
Pre-op time(minutes)	305	275	0.524
Op. time(minutes)	45	41	0.356
Type of appendicitis (%)			0.759
Acute	24	24	
Suppurative	48	56	
Gangrene	10	6	
Ruptured	18	14	
Degree of contamination (%)			0.722
Mild	80	86	
Moderate	12	8	
Severe	8	6	

**Table 4.** Outcome of both interventions group

	Vicryl	Vicryl Plus	p-value
SSI (cases)	4 (8%)	5 (10%)	0.727
Superficial	3	5	
Deep	1	0	
Organ/space	0	0	
Culture	1 (deep) <i>P. aeruginosa</i>	1 <i>S. aureus</i>	
LOS (day)	3.7	3.7	0.500

**Table 5.** Comparable data between infected and non-infected group

	Non-infected (99)	Infected (9)	p-value
Age (year)	29	33	0.331
Temp (°C)	37.5	37.8	0.327
WBC (cell/mm <sup>3</sup> )	15,755	16,277	0.686
PMN (%)	82	86	0.123
Op. time (minutes)	43	45	0.772
Type (cases)	Suppurative 50/91 Ruptured 11/91	Suppurative 2/9 Ruptured 5/9	0.050 0.007
LOS (days)	3.6	7.4	0.006

## Discussion

Surgical site infection is the most common complication of appendectomy. Wound infections cause pain, lengthy hospital stay and increased hospital bill<sup>(6)</sup>. The present study showed that the surgical site infection rate at Thammasat University Hospital was 8%, which was slightly higher than the standard rate at 6.4%<sup>(10)</sup>. The average rate of surgical site infection in Thailand was previously reported at 1.2% and the operative time was a determining factor in surgical site infection<sup>(11)</sup>. In contrast, the present study showed no difference in the operative time of infected and uninfected groups. The average operative time was 43 minutes, which was shorter than the national average time of 58 minutes. A major factor for an infection at surgical wounds was the type of appendicitis. The surgical site infections were primarily found in patients with ruptured appendicitis. Additionally, an infection ratio between men and women were 3:2 in the present study and was different from an equal infection ratio (1:1) of the previous study<sup>(11)</sup>.

The infection at surgical sites is a major problem in surgical patients. It was found that sutures play a role in surgical site infection<sup>(1)</sup>. Ninety percent of infection occurs at superficial and deep layer of surgical wounds. In the absence of sutures, the surgical site infection occurred when there were 10,000-100,000 CFU/mg of bacteria; however, if sutures were used, the presence of only 100 CFU/mg could cause the surgical site infection. It was hypothesized that the human body recognized the suture as a foreign body. Bacteria attached to a suture and subsequently formed biofilm, which promoted attachment and interfered with the immune system<sup>(1)</sup>. Several methods were developed to prevent the surgical site infection including prophylactic antibiotic use<sup>(11)</sup>, use of absorbable suture or non-absorbable monofilament suture<sup>(6)</sup>, and laparoscopy<sup>(7)</sup>. However, some techniques such as

application of Betadine before wound closure were not effective<sup>(8)</sup>. Due to the importance of suture, suture coated with Triclosan was developed. Triclosan is a broad-spectrum antiseptic and has been used for over 30 years. It has antimicrobial activity against *S. aureus*, *S. epidermidis*, MRSA, MRSE, Vancomycin resistant *Enterococcus fecalis*, *Pseudomonas aeruginosa* and *E. coli*<sup>(3,4)</sup>. Polyglactin 910 (Vicryl®), a commonly used suture, is coated with Triclosan and is sold under the trade name of Vicryl Plus®. Both *in vitro* and animal experiments showed that Vicryl Plus was capable to inhibit more than 50% of microorganisms that caused surgical site infection<sup>(1,3,4)</sup>, had no effect on wound healing<sup>(1,12)</sup> and did not have carcinogenic potential, genotoxicity and sensitization potential<sup>(2)</sup>. Knot property and tensile strength of Vicryl Plus were studied<sup>(13)</sup>. Vicryl Plus has been used in veterinary practice and was found to be effective in prevention of surgical site infection<sup>(1,3,4,14)</sup>. However, there were reports on tissue reaction caused by Vicryl and Vicryl Plus. These reactions happened rarely and equally between Vicryl and Vicryl Plus, suggesting that it was not caused by Triclosan but probably resulted from a contamination<sup>(15)</sup>.

There was only one randomized control trial by Ford HR and colleagues<sup>(5)</sup> that studied Vicryl and Vicryl Plus in various operations in children age 1 to 18 years old. However, the present study was focused on physical properties including knot property, tensile strength, and wound healing, but did not compare their effects on the prevention of surgical site infection. This is the first report that investigated whether Triclosan-coated suture can reduce the surgical site infection in humans.

The authors found that surgeons could not separate Vicryl and Vicryl Plus sutures due to their similar appearance. There were no differences in knotting, cutting, and strength of knot. After follow-up

for 1 year, the authors found no allergy or adverse effects, indicating that it is safe to use in patients.

Additionally, the authors found that patients with complicated appendicitis especially ruptured appendicitis had higher rate of infection than other groups, which is similar to a previous report<sup>(16)</sup>. Therefore, the correct diagnosis before the appendix is ruptured and various prevention methods for surgical site infection are critical. Most patients are in the working age group. The surgical site infection can lead to longer hospitalization time, greater hospital cost, as well as the loss of income.

### Conclusion

Coated polyglactin 910 with triclosan (Vicryl Plus) was safe and satisfactory in surgical practice. Surgical site infection of appendectomy seemed to be comparable between coated polyglactin 910 with triclosan (Vicryl Plus) and traditional polyglactin 910 (Vicryl) group. A complete study is required for final conclusion after the safety of the new suture is confirmed.

### Completing interests

The authors declare that they have no completing interests.

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**การศึกษาเบื้องต้นด้านความปลอดภัยของการใช้วัสดุในการเย็บแผลโพลีแกรกติน 910 ที่เคลือบด้วยสารยับยั้งเชื้อโรคไตรโคซาน (ไวคริล พลัส) เปรียบเทียบกับที่ไม่ได้เคลือบ (ไวคริล) เพื่อช่วยลดการติดเชื้อแผลผ่าตัดไส้ติ่งอักเสบ: การศึกษาแบบสุ่มไปข้างหน้า**

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**วัตถุประสงค์:** เป็นการศึกษาเปรียบเทียบประสิทธิภาพในการลดการติดเชื้อแผลผ่าตัดของ วัสดุเย็บแผลโพลีแกรกติน 910 ที่เคลือบด้วยสารยับยั้งเชื้อโรคไตรโคซาน (Vicryl Plus) เปรียบเทียบกับที่ไม่ได้เคลือบ (Vicryl) ในผู้ป่วยผ่าตัดไส้ติ่งอักเสบ

**วัสดุและวิธีการ:** ผู้ป่วยไส้ติ่งอักเสบภายหลังได้รับการผ่าตัดไส้ติ่งออกแล้วจะได้รับการสุ่มแบ่งออกเป็น 2 กลุ่ม โดยกลุ่มที่หนึ่ง ใช้โพลีแกรกติน 910 ที่เคลือบด้วยสารยับยั้งเชื้อโรคไตรโคซาน (Vicryl Plus) เบอร์ 2/0 ในการเย็บผนังหน้าท้อง ส่วนกลุ่มที่สองจะใช้โพลีแกรกติน 910 (Vicryl) เย็บแทน จากนั้นจะมีการติดตามดูการติดเชื้อแผลผ่าตัดจนครบ 30 วัน 6 เดือน และ 1 ปีโดยทั้งผู้ที่เย็บและผู้ประเมินจะไม่ทราบชนิดของวัสดุที่ใช้ เป็นการศึกษาเบื้องต้นของผู้ป่วย 100 ราย

**ผลการศึกษา:** ทำการศึกษาตั้งแต่เดือน สิงหาคม พ.ศ. 2549 ถึง มีนาคม พ.ศ. 2550 มีผู้เข้าร่วมการศึกษา 100 ราย พบว่าอัตราการติดเชื้อ แผลผ่าตัดในผู้ป่วยไส้ติ่งอักเสบเท่ากับ 8% เปรียบเทียบอัตราการติดเชื้อแผลผ่าตัดระหว่างการ ใช้ Vicryl และ Vicryl Plus พบว่าอยู่ที่ 8% และ 10% ซึ่งไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ( $p = 0.05$ ) โดยมี 1 รายที่พบเป็นการติดเชื้อแผลผ่าตัดชั้นลึก (deep SSI) ในกลุ่มผู้ป่วยที่ใช้ Vicryl Plus ในการเย็บแผลสำหรับระยะเวลาในการนอน รักษาตัวในโรงพยาบาลทั้งสองกลุ่มก็ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ( $p = 0.05$ )

ในการติดตามภาวะแทรกซ้อนจากกลุ่มผู้ป่วยที่ใช้ Vicryl plus ไม่พบภาวะแทรกซ้อนใดๆ และจากการสอบถามแพทย์ผู้ผ่าตัดก็ไม่พบความแตกต่างของวัสดุเย็บแผลทั้งสองชนิด

**สรุป:** รายงานเบื้องต้นจากการศึกษาการใช้ Vicryl plus เย็บแผลผ่าตัดไส้ติ่งอักเสบพบว่ามีความปลอดภัย ไม่พบภาวะแทรกซ้อนใด ๆ และไม่มี ความแตกต่างในแง่การผูก ความแข็งแรงทนทาน เมื่อนำมาเปรียบเทียบกับ การใช้ Vicryl ผลเบื้องต้นพบว่าไม่ช่วยลดการติดเชื้อแผลผ่าตัด

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