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Predictors of Wound Infection in Elective Colorectal Surgery. Multicenter Observational Case–Control Study☆

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ABSTRACT

Introduction: The aim of this study is to evaluate the usefulness of Vicryl Plus® suture in reducing the rate of postoperative wound infection in elective colorectal surgery.
Methods: A prospective case–control multicenter study with 480 patients undergoing elective colorectal surgery was performed between 2006 and 2007. Patients were divided in 2 groups of equal sample size: group 1, closure of the abdominal wall using Vicryl Plus® and group 2 where PDS II® was used. The study involved 5 hospitals in the Spanish State. Wound infection was classified into superficial and deep. All patients diagnosed of wound infection during the hospital stay and up to 30 days after discharge were studied. For the statistical analysis Chi-square test and Fisher exact were used for bivariate analysis and logistic regression model for multivariate analysis.
Results: Wound infection rates were significantly lower in group 1: 14.6 vs 29.2. Multivariate analysis showed that risk of wound infection was higher in patients with cancer, lung disease, anemia, operative time greater than 2 h, lack of second dose intra-operative prophylactic antibiotic and laparotomy closure with PDS suture II®.
Conclusions: The use of suture coated with triclosan can be an effective prophylactic tool in reducing wound infection rate in patients undergoing elective colorectal surgery.
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Factores predictivos de infección de herida en cirugía colorrectal. Estudio observacional multicéntrico de casos y controles

Palabras clave:
Cirugía colorrectal
Infección herida quirúrgica
Infección de órgano y espacio
Vicryl Plus

RESUMEN

Introducción: El objetivo de este estudio es evaluar la utilidad del material de sutura Vicryl Plus® en reducir la tasa de infección de herida postoperatoria en cirugía colorrectal electiva.
Método: Estudio de casos y controles prospectivo multicéntrico sobre 480 pacientes intervenidos de cirugía colorrectal electiva entre el 2006 y 2007, divididos en 2 grupos de igual tamaño muestral, sometidos a cierre de pared abdominal mediante uso de Vicryl Plus® (grupo 1) y PDS II® (grupo 2). En el estudio participaron 5 centros hospitalarios del Estado Español. La infección de herida fue clasificada en superficial y profunda. Fueron incluidos todos los pacientes diagnosticados de infección de herida durante la estancia hospitalaria y hasta 30 días después del alta. Para el estudio estadístico fueron utilizados el test del Chi-cuadrado y el exacto de Fisher para el análisis bivariante y el modelo de regresión logística para el análisis multivariante.
Resultados: La tasa de infección de herida observada fue significativamente inferior en el grupo 1: 14,6 frente al 29,2 del grupo 2. Según el estudio multivariante, el riesgo de infección de herida es superior en los pacientes con neoplasia, enfermedad pulmonar, anemia, tiempo operatorio superior a 2 h, falta de segunda dosis profiláctica intraoperatoria y cierre de laparotomía con sutura de PDS II®.
Conclusiones: El uso de material de sutura recubierto de triclosan puede ser una herramienta profiláctica eficaz para disminuir la tasa de infección de herida operatoria en los pacientes intervenidos mediante cirugía colorrectal electiva.

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Introduction

Wound infection is the most common complication among patients undergoing elective colorectal surgery; it has a significant impact on morbidity and health care costs. Incidence varies between 5% and 40%; the main reason for this discrepancy depends on whether infections occurring after hospital discharge are included or not.[1–5] The etiology of surgical infection is multifactorial and results from the interaction of many variables related to the patient, germ, intervention and hospitalization. Diabetes, malnutrition, immunosuppression, obesity, anemia and transfusion have been the main risk factors studied.[6–20]

Other causes have been related to the surgical intervention, such as hypothermia, hypoxia, surgery type, bowel preparation, procedure duration, use of wall protection methods, antibiotic prophylaxis and the time of administration.[6–13] In recent years, there has been growing interest in how suture materials influence wound infection development. The hypothesis is that suture materials favor bacterial colonization, reducing local and systemic therapeutic measure effectiveness.[8] Vicryl Plus® is a suture thread coated with triclosan to fight Gram-positive and Gram-negative bacteria, thus reducing the potential for infection initiation and propagation; in vitro studies and animal models have demonstrated its effectiveness.[14–19] However, there is less scientific evidence of its efficacy from a clinical point of view. This study has aimed mainly to evaluate the possible clinical benefit of Vicryl Plus® in reducing wound infection rates and decreasing hospital stay for patients with infected wounds from elective colorectal surgery laparotomy closures.

Method

In order to assess the actual benefit of a suture material with antiseptic properties on laparotomy closures, a prospective case–control study was conducted including patients who underwent surgery for elective colorectal disease in 2006–2007. The study group comprised 240 consecutive patients who underwent abdominal wall closure with Vicryl Plus® (Triclosan, Ethicon Deutschland, Norderstedt, Germany coated antibacterial polyglactin 910), whereas the control group comprised 240 patients who underwent laparotomy closure with conventional PDSII suture® (Polydioxanone, Ethicon Deutschland, Norderstedt, Germany). Control patients were selected retrospectively with the same inclusion and exclusion criteria of the studied group. All surgical procedures included were classified as clean-contaminated surgery. The study excluded patients with emergency colorectal resection, colorectal disease with multivisceral resection, and contaminated colorectal surgery cases. Wound infection was defined as spontaneous drainage of purulent material from the wound or from the surgeon's deliberate revision and positive culture of drained serous fluid. Infections were classified as superficial (skin and subcutaneous tissue), and deep (fascia and muscle tissue). All wound infection cases diagnosed during hospital stays were included, and those up to 30 days after discharge, diagnosed during ambulatory follow-up. Patients were classified based on malignant etiology (neoplasia) and benign etiology (diverticular and inflammatory bowel disease). Different variables considered as potential risk factors for surgical infection were studied by bivariate analysis: age over 70 years, malignant etiology, diabetes, chronic renal insufficiency (serum creatinine>1.2 mg/dL), hypoalbuminemia

(serum albumin<3.5 g/dL), obesity (BMI>30 kg/m^2), anemia (hemoglobin<12 g/dL), concomitant steroid therapy, and chronic lung disease. Evaluated surgical variables were: surgery duration longer than 2 h, administration of a second dose of intraoperative antibiotic prophylaxis, and using Vicryl Plus® for laparotomy closure.

Statistical Analysis

For the categorical variable study, Chi-square and Fisher's exact tests were used, based on application conditions. The Mann–Whitney *U* test was used to analyze quantitative variables. Odds ratios were used to measure associations. The multivariate logistic regression method and the Hosmer and Lomeshow test were applied to study the relationship between dependent and independent variables.

Results

Study Group Characteristics

Characteristics of patients in the 2 study groups are reported in Table 1. Average patient age for the case group was 64.2 years (18–86 year range), and 65 years for the control group (20–89 year range). Not all variables considered were homogeneous in the 2 groups. Differences were found regarding etiology, anemia, obesity, surgery duration, and administration of a second antibiotic dose at 3 h. after surgery. Neoplasm was the most common etiology in both groups: 92.1% (221/240) for the case group, and 85.4% (205/240) for the control group (P=.021). 26.7% (64/240) of patients in the Vicryl Plus® group had anemia, compared to 9.2% (22/240) of the PDS II® group (P<.001). A BMI greater than 30 kg/m^2 was observed in 3.8% (9/240) of patients in the case group, and 12.5% (30/240) of patients in the control group (P<.001). Surgery duration was greater than 2 h for 77.5% (186/240), and 99.2% (238/240) of patients, respectively (P<.001). All patients received antibiotic prophylaxis during induction of anesthesia; 75.4% (181/240) of cases in the Vicryl Plus ® group, and 85.8% (206/240) of cases in the PDSII® group, received a second antibiotic dose at 3 h. after surgery (P=.004). Abdominal wall protection was applied during each surgical procedure.

Wound Infection Risk Factors

The bivariate study on different variables showed that the wound infection rate was significantly higher in cancer patients and chronic lung disease patients, if the surgery exceeded 2 h, in the event that no second antibiotic dose was administered at 3 h after surgery, and for laparotomy closures with conventional suture (PDS II®) (Table 2).

The multivariate analysis of the variables identified as potential surgical infection risk factors, and the non-homogeneous variables resulting from comparing the 2 groups, showed that the wound infection risk was 2.95 times higher in cancer patients, 2.97 times higher in chronic obstructive pulmonary disease patients, 2.33 times higher in anemia patients, 4.76 times higher if surgery exceeded 3 h, 3.02 times higher if no second antibiotic dose was administered during surgery, and 1.85 times with conventional suture compared to Vicryl Plus® (Table 3).

Main Results

The overall wound infection rate after wall closure with Vicryl Plus® was significantly lower compared to closure with PDS II1. Eleven cases of infection (31.4%) were diagnosed after hospital discharge.

Patients who suffered wound infections had longer hospital stays than patients who did not: 21.2 compared to 9.7 days (P<.001). However, for cases of wound infection, the average stay of patients in the Vicryl Plus® group was significantly lower than for those in the PDS II® group (Table 4).

Discussion

In this study, the authors wanted to evaluate the impact of several risk factors for wound infection in elective colorectal surgery, with special emphasis on the influence of the suture material used for laparotomy closure. Short-medium absorption suture such as Vicryl Plus® was used, rather than long-absorption monofilament suture, due to the fact that it was the only available triclosan coated suture at the time of the study.

Various research projects have studied triclosan's antibacterial activity, in vitro and with animals.[15–19] Other studies tested biocompatibility and safety of triclosan-coated 910 Polyglactil for clinical use.[14,21] Ford et al. demonstrated the efficacy of Vicryl Plus® in pediatric patients with a randomized clinical trial.[22] A systematic review published in 2012 showed no significant differences between Vicryl® with and without triclosan, considering a large sample of 836 patients derived from a pooled analysis of 7 randomized studies.[23] Moreover, a subsequent meta-analysis with greater statistical power, including 17 randomized studies, showed a significant benefit from triclosan-coated sutures in clean-contaminated abdominal surgery and in adult patients.[24] Nakamura et al. have recently published a randomized prospective study on the effects of Vicryl Plus® on elective colorectal surgery, demonstrating a significant decrease in the rate of surgical infection compared to patients where Vicryl® without triclosan was used, 4.3% compared to 9.3%.[25]

One of the limitations of this study is related to the characteristics of the patients. Some of the variables were significantly different for the comparative analysis of the 2 groups. These differences are probably due to the fact that they are 2 consecutive series of patients. To reduce the influence of this bias on study results, a multivariate analysis was performed to determine the influence of variables potentially involved in surgical site infection.

In our experience, patients treated with Vicryl Plus® had a 14.6% wound infection rate, significantly lower compared to 29.2% for the group treated with PDSII®. In a 2009 prospective study comparing Vicryl Plus® to PDSII®, Justinger et al. reported a significantly lower wound infection rate using Vicryl Plus®: 4.9% compared to 10.8%.[26] However, the study

Table 1 – Characteristics of Patients in the 2 Groups.

Variables	Vicryl Plus		PDS II		P-value*
	No.	%	No.	%	
Gender					
Male	154	64.2	150	62.5	.705
Female	86	35.8	90	37.5	
Diagnosis					
Malignant	221	92.1	205	85.4	.021
Benign	19	7.9	35	14.6	
Corticosteroids					
No	226	94.2	224	93.3	.706
Yes	14	5.8	16	6.7	
Hypertension					
No	159	66.3	133	55.4	.015
Yes	81	33.8	107	44.6	
Diabetes					
No	204	85.0	203	84.6	.899
Yes	36	15.0	37	15.4	
Kidney failure					
No	234	97.5	234	97.5	1.000
Yes	6	2.5	6	2.5	
Hypoalbuminemia					
No	222	92.5	225	93.8	.588
Yes	18	7.5	15	6.3	
Anemia					
No	176	73.3	218	90.8	<.001
Yes	64	26.7	22	9.2	
Obesity					
No	231	96.3	210	87.5	<.001
Yes	9	3.8	30	12.5	
Elderly					
< 70 years	134	55.8	144	60.0	.355
≥70 years	106	44.2	96	40.0	
Lung disease					
No	215	89.6	203	84.6	.102
Yes	25	10.4	37	15.4	
Surgery duration					
Less than 2 h.	54	22.5	2	.8	<.001
More than 2 h	186	77.5	238	99.2	
2nd antibiotic dose					
No	60	25.0	34	14.2	<.001
Yes	180	75.0	206	85.8	

* Chi-square test.

included non-homogeneous patients due to the inclusion of different procedures, surgery contamination degree and surgical setting: hepatobiliopancreatic, intestinal, colorectal, vascular surgeries, as well as elective and emergency surgeries. In this study, the derivative impact of using Vicryl Plus® was evaluated, specifically in elective colorectal surgery on a series of 240 consecutive patients prospectively included. In order to increase the significance and consistency of the results, a control sample of patients was considered; they were included based on the same patient inclusion criteria in the group of interest; patients in the control group were treated with laparotomy closure using PDSII®, because it is a very commonly used suture and conventionally used by surgeons belonging to the group of authors.

Eleven wound infection cases were diagnosed after hospital discharge. According to the results of a study by Smith et al., 49% of the wound infections in the patients included were diagnosed after discharge.[4] The reason for the lack of consistency in the results in the literature may lie in the different system used to record wound infections; probably, the series with higher infection rates also include cases observed after hospital discharge.

In this study, the bivariate analysis showed that using Vicryl Plus® produced a significant reduction in wound infections, with a 14.6[%] rate, compared to 29.2% when using PDSII®.

However, the risk of infection was also found to be associated with other factors such as cancer, chronic

Table 2 – Variables Related to Wound Infection.

Variable	No. of patients	Infection cases	%	P*
Gender				
Male	304	65	21.4	.731
Female	176	40	22.7	
Diagnosis				
Malignant	426	87	20.4	.031
Benign	54	18	33.3	
Corticosteroids				
No	450	96	21.3	.266
Yes	30	9	30.0	
Hypertension				
No	292	61	20.9	.515
Yes	188	44	23.4	
Diabetes				
No	407	85	20.9	.215
Yes	73	20	27.4	
Kidney failure				
No	468	103	22.0	1.000
Yes	12	2	16.7	
Hypoalbuminemia				
No	447	96	21.5	.437
Yes	33	9	27.3	
Anemia				
No	394	83	21.1	.359
Yes	86	22	25.6	
Obesity				
No	441	95	21.5	.553
Yes	39	10	25.6	
Elderly				
<70 years	278	60	21.6	.856
≥70 years	202	45	22.3	
Lung disease				
No	418	79	18.9	<.001
Yes	62	26	41.9	
Surgery duration				
Less than 2 h	56	4	7.1	.005
More than 2 h	424	101	23.8	
2nd antibiotic dose				
No	214	35	16.4	.009
Yes	266	70	26.3	
Use of Vicryl Plus®				
No	240	70	29.2	<.001
Yes	240	35	14.6	

* Chi-square test and Fisher exact test.

Table 3 – Multivariate Analysis: Factors Related to Surgical Infection.

Risk factors	RO	RO 95 CI Min	RO 95 CI Max	P
Malignant etiology	2.955	1.495	5.843	.002
Lung disease	2.976	1.644	5.390	.000
Anemia	2.336	1.224	4.458	.010
Surgery duration >2 h	4.768	1.506	15.093	.008
2nd antibiotic dose	3.023	1.452	6.291	.003
No Vicryl Plus®	1.853	1.106	3.104	.019

pulmonary disease, surgery duration exceeding 2 h, and no administration of a second prophylactic antibiotic dose at 3 h. after surgery. For that reason, and because of the incomplete homogeneity of the 2 study groups, we applied a multivariate analysis; using Vicryl Plus proved to be a useful independent preventive measure; the risk of wound infection being 1.85 times higher in patients treated with polydioxanone suture. Other factors such as neoplastic etiology, chronic lung disease, anemia, surgery duration exceeding 2 h, and failure to administer an additional antibiotic prophylaxis dose at 3 h. after surgery were also associated with increased infection risk.

Table 4 – Results.

Results	Vicryl Plus® %	PDS II® %	P
Wound infection	14.6 (35/240)	29.2 (70/240)	<.001*
Superficial infection	13.8 (33/240)	27.1 (65/240)	<.001*
Deep infection	0.8 (2/240)	2.1 (5/240)	.450*
Evisceration	0.8 (2/240)	2.5 (6/240)	.285*
Stay (days)	13.7	23.5	.049**

* Chi-square test and Fisher exact test.
** Mann–Whitney *U* test.

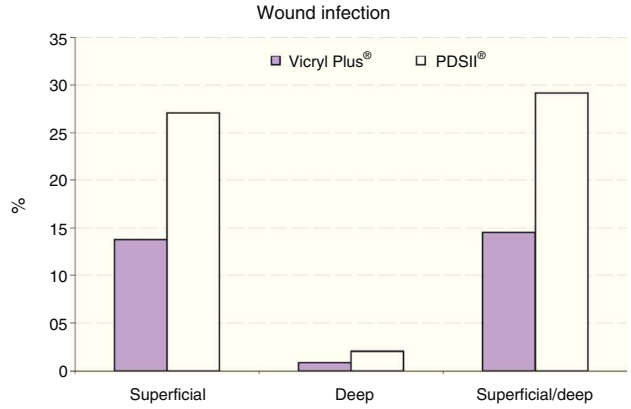

Fig. 1 – Surgical infection.

An important finding was the significant difference in hospital stay between patients with wound infections in the group treated with Vicryl Plus® compared to patients with infections in the control group: 13.7 and 23.5 days, respectively. This result suggests the possibility that the bacteriostatic effect of triclosan favors less colonization of the suture material by the microorganisms, therefore allowing for faster response to the medical treatment of the infection.

Given that this study is non-randomized, it is limited to highlighting the differences in results in terms of wound infection, comparing the use of Vicryl Plus® and PDSII®.

The results shown indicate that using 910 Polyglactil with triclosan in clean-contaminated surgery, such as elective colorectal surgery, helps reduce abdominal wall infection rate, and consequently, hospital stays and healthcare costs. Additional randomized studies are needed to corroborate our findings (Fig. 1).

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