Randomized Controlled Trial of the Use of a Large-pore Polypropylene Mesh to Prevent Incisional Hernia in Colorectal Surgery

Miguel Ángel García-Ureña, PhD, MD, Javier López-Monclús, MD,* Luis Alberto Blázquez Hernando, MD,* Daniel Melero Montes, MD,* Alvaro Robín Valle de Lersundi, PhD, MD,* Camilo Castellón Pavón, PhD, MD,† Carmen Jiménez Ceinos, MD,* and Patricia López Quindós, MD**

Objective: To reduce the incidence of incisional hernia (IH) in colorectal surgery by implanting a mesh on the overlay position.

Background: The incidence of IH in colorectal surgery may be as high as 40%. IH causes severe health and cosmetic problems, and its repair increases health care costs.

Material and Methods: Randomized, controlled, prospective trial. Patients undergoing any colorectal procedure (both elective and emergency) through a midline laparotomy were divided into 2 groups. The abdomen was closed with an identical technique in both groups, except for the implantation of an overlay large-pore polypropylene mesh in the study group. Patients were followed up clinically and radiologically for 24 months.

Results: A total of 107 patients were included: 53 in the study group and 54 in the control group. Both groups were homogeneous, except for a higher incidence of diabetes in the mesh group. There were 20 emergency procedures in the study group and 17 in the control group. There were no statistical differences in surgical site infections, seromas, or mortality between the groups (33.3%, 13.8%, and 3.7% in the control group and 18.9%, 13.2%, and 3.8% in the study group). No mesh rejection was reported. The incidence of IH was 17 of 54 (31.5%) in the control group and 6 of 53 (11.3%) in the study group ($P = 0.011$).

Conclusions: The incidence of IH is high in patients undergoing elective or emergency surgery for colorectal diseases. The addition of a prophylactic large-pore polypropylene mesh on the overlay position decreases the incidence of IH without adding morbidity.

Keywords: abdominal wall, colorectal surgery, incisional hernia, polypropylene mesh, prophylactic mesh

(*Ann Surg* 2015;261:876–881)

Despite the increasing use of laparoscopic approach in surgery, midline laparotomy is still commonly used in both elective and emergency situations. The prevalence of incisional hernias (IHs) is high after elective midline laparotomy, with published rates between 10% and 40%.[1,2] The risk of IH is even higher when emergency surgery is performed, with an incidence of up to 54%.[3]

IH may lead to severe complications, such as bowel obstruction, incarceration, or strangulation.[4] It also causes cosmetic problems, patient dissatisfaction, and symptomatology that impair physical activity and quality of life. To avoid the risk of complications and alleviate symptomatology, elective surgical repair is indicated in most patients with IH. This means a new hospital admission and a surgical procedure, with associated financial and social burdens. Furthermore, this new surgery does not guarantee solution of the problem because of the high recurrence rates and complications associated with the repair and the use of meshes.[5] Therefore, prevention seems to be the best solution to reduce the problem of IH. To date, all research efforts have focused on laparotomy closure technique with different types of sutures and technical improvements such as the use of running sutures, loose stitches, and retaining or mass sutures.[6]

In the last 10 years, initial satisfactory results with the use of a prophylactic polypropylene mesh have been published in some subgroups of patients at risk of developing ventral hernias: clean vascular surgery for aneurysm, clean-contaminated surgery for obesity, surgical procedures in selected patients with risk factors, and even contaminated emergency surgery.[7–14]

Patients with stomas are another group of patients in whom mesh prevention has been studied. There have been several randomized clinical trials (RCTs) evaluating the use of lightweight meshes to reduce the incidence of parastomal hernias, in which the safety and efficacy of a prophylactic mesh have been assessed.[15–18]

We hypothesized that a strategy of prophylactic mesh placement on an overlay position in every patient undergoing midline laparotomy for colorectal diseases would reduce the incidence of IH, maintaining similar rates of wound complications. The aim of our study was to quantify the reduction in the incidence of IH after prophylactic mesh placement and to assess its safety.

MATERIALS AND METHODS

A prospective, randomized, clinical trial was conducted in the Department of General Surgery of Henares University Hospital in Madrid, Spain. This general hospital is a 200-bed facility that belongs to the Spanish National Health Service and attends a 160,000 population in the periphery of Madrid. The surgical team comprised 12 surgeons with specialization in general and digestive surgery.

The main purpose of the study was to determine whether a mesh was effective and safe in the prevention of midline IH in patients undergoing colorectal surgery. The study was approved by the local ethics committee, and informed consent from patients was obtained. It was registered under NCT01788826 on clinicaltrials.gov.

Inclusion criteria were patients older than 18 years, operated on any colorectal disease (both elective and emergency surgical procedures) through a midline laparotomy since June 2009. Exclusion criteria were the presence of previous IH, intraoperative carcinomatosis finding, and hemodynamic instability during the surgical procedure. Patients were enrolled by any of the surgeons after diagnosis.

From the *Department of Surgery, Henares University Hospital, and †Department of Surgery, Infanta Elena University Hospital, Francisco de Vitoria University, Madrid, Spain.

Disclosure: The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citation appears in the printed text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

Reprints: Miguel Ángel García-Ureña, PhD, MD, Department of Surgery, Henares University Hospital, Francisco de Vitoria University, Avenida de Marie Curie, s/n, 28822 Coslada, Madrid, Spain. E-mail: magurena@gmail.com.

ISSN: 0003-4932/15/26105-0876
DOI: 10.1097/SLA.0000000000001116