ผลงานด้านวิชาการและการวิจัย

กลุ่มอนามัยแม่และเด็ก สำนักส่งเสริมสุขภาพ

.....

ชื่อ-นามสกุล นายแพทย์โอฬาริก มุสิกวงศ์ **ตำแหน่ง** นายแพทย์ชำนาญการ

เรื่อง The Future of Adhesion Prophylaxis Trials in Abdominal Surgery: An Expert Global Consensus

Abstract: Postoperative adhesions represent a frequent complication of abdominal surgery. Adhesions can result from infection, ischemia, and foreign body reaction, but commonly develop after any surgical procedure. The morbidity caused by adhesions affects quality of life and, therefore, it is paramount to continue to raise awareness and scientific recognition of the burden of adhesions in healthcare and clinical research. This 2021 Global Expert Consensus Group worked together to produce consented statements to guide future clinical research trials and advise regulatory authorities. It is critical to harmonize the expectations of research, to both develop and bring to market improved anti-adhesion therapies, with the ultimate, shared goal of improved patient outcomes.

Introduction

Postoperative adhesions represent a frequent complication of abdominal surgery. Adhesions can result from infection, ischemia, and foreign body reaction, but commonly develop after any surgical procedure. Indeed, abdominal, and pelvic surgeries are the most common cause of peritoneal adhesions and remain a source of considerable morbidity. Among these patients, 66–79% develop adhesions following abdominal and pelvic surgeries.The most common complications of postoperative adhesions are difficulty at reoperations, small bowel obstruction, pelvic pain, and female infertility. The economic consequences of morbidity caused by adhesions are well-documented: longer hospitalization or rehospitalization and patients' reduced quality of life. The data from the 2020-SCAR-update study demonstrate that 1 in 4 patients in whom abdominal or pelvic open surgery was performed were readmitted to hospital within 5 years of the initial procedure for adhesion-related causes or subsequent surgery were complicated by adhesions. The data suggest that laparoscopic procedures decrease readmission to the hospital by 30%, but the morbidity and associated factors remain substantial. As a result of pre-existing adhesions, following surgeries can be more time consuming and challenging, posing increased risk to the patient [5]. Up to 60% of surgeries performed today are repeat surgeries and up to 20% of patients undergoing operative adhesiolysis suffer an inadvertent enterotomy. The morbidity caused by adhesions affects

quality of life and, therefore, it is paramount to continue to raise awareness and scientific recognition of the burden of adhesions in healthcare and clinical research.

The objective of this paper is to set the stage for the next frontier of adhesion prevention, moving beyond barriers and into pharmaceuticals that begin to address the key cellular targets implicated in adhesion prevention. This paradigm shift requires rethinking on how trials are conducted; regulatory agencies', particularly the drug division; perspectives and expectations as to incorporating clinical trial endpoints that take into account the patients' voice and perspective (as per the Patient Focused Drug Development initiative launched by the U.S. Food and Drug Administration (FDA)); and how clinical researchers may look at advancing the field in assessing how reduction or complete prevention translates to clinically relevant outcomes. This consensus document, as an expert opinion paper, offers recommendations on how to conduct clinical drug trial research and defines the components of a strong clinical study design, including relevant primary and secondary endpoints that can be measured in the population within a reasonable period.

Conclusions

Adhesions are anticipated sequelae of most pelvic and abdominal surgeries. Current FDA-approved adhesion prevention products do not target the pathophysiology of adhesion formation and could therefore be associated with reduced efficacy. The burdens and consequences of adhesions are well-studied; yet clinical trial research on preventing adhesions has been woeful and stagnant, partly due to regulatory challenges. In the 2010 Adhesion Prevention and Reduction Consensus statement, the panel strongly prioritized improvements in "validated and clinically relevant scale(s) to assess intra-abdominal adhesions" and development of safe and effective anti-adhesion methods. This 2021 Global. Expert Consensus Group agrees with these statements and worked together to produce consented statements to guide future clinical research trials and advise regulatory authorities. It is critical for researchers and regulatory authorities to harmonize the expectations of research, to both develop and bring to market improved anti-adhesion therapies, with the ultimate, shared goal of improved patient outcomes.

ช่องทางการเผยแพร่

Journal of Clinical Medicine, Published: 8 March 2022 (https://www.mdpi.com/1533020)

ผ่านความเห็นชอบ

(นายแพทย์โอฬาริก มุสิกวงศ์)

หัวหน้ากลุ่มอนามัยแม่และเด็ก สำนักส่งเสริมสุขภาพ