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Pasireotide for the Prevention of Postoperative Pancreatic Fistula: A Debate Not To Close Too Early



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We read with great interest the article written by Kunstman and colleagues entitled, “Outcomes after pancreatectomy with routine pasireotide usage.”¹ The authors presented a single-center, prospective, nonrandomized study with the primary aim of assessing the incidence of clinically relevant postoperative pancreatic fistula (CR-POPF) and abscess formation in patients undergoing pancreatic resection since the initiation of routine perioperative pasireotide administration.¹ Their study compared a pasireotide group of 652 patients to the placebo group of the original randomized trial, previously published by the same authors.^{1,2} They concluded that pasireotide allowed a marked reduction in the rate of clinically significant abscesses and POPF (a statistically significant absolute risk reduction of 7.6%, from 20.9% in the placebo group to 13.3% in pasireotide group), confirming the effect observed in the randomized trial of 2014.^{1,2}

In 2014, Allen and colleagues² thrilled the scientific community with their randomized, double-blind, placebo-controlled trial that demonstrated the ability of pasireotide to significantly reduce the CR-POPF rate (a statistically significant absolute risk reduction of 12%, from 21% in the

placebo group to 9% in pasireotide group). We all thought we finally got a solution to the heavy problem of pancreatic fistula after pancreatic resection. This understandable enthusiasm had quickly directed the attention of some authors on cost-effectiveness analysis, “almost forgetting” the evaluation of the real effectiveness of the drug.³

However, in a short time, the results obtained by studies published later, with the aim of analyzing the effect of pasireotide on the prevention of POPF, discouraged the scientific community.^{3–6} In particular, the single-center, prospective, nonrandomized studies published by Dominguez-Rosado and colleagues,⁴ Elliott and associates,⁵ and Young and coauthors⁶ were relevant. By comparing the pasireotide group (of 127, 111, and 116 patients, respectively) with historical control groups, similar results emerged: there were no statistically significant differences in terms of CR-POPF rate, CR-POPF rate in different cohorts of patients (pancreaticoduodenectomies, distal pancreatectomies, and pancreaticoduodenectomies with high fistula risk score), length of hospitalization, postoperative complication, readmission, and mortality rate.^{4–6}

Therefore, publication of the study by Kunstman and colleagues,¹ albeit with the limitations of a nonrandomized study but with a far broader pasireotide group than in previous nonrandomized studies, “has rekindled the community’s hope.”

Therefore, we emphasize how important it is not to quickly set aside pasireotide and its potential benefits, which must be studied extensively through multicentric, nonsponsored, randomized, controlled trials using the International Study Group for Pancreatic Fistula (ISGPF) grading system for the assessment of CR-POPF severity.

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