Title:

Reduction in Surgical Site Infections by Localized Administration with D-PLEX$_{100}$ in Patients with Multiple Risk Factors Undergoing Colorectal Surgery

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Background:

The incidence of surgical site infection (SSI) for colorectal surgery can be as high as 43% due to contamination risk of the procedure and patient related risk factors. D-PLEX$_{100}$ is a novel drug-eluting lipid polymer matrix that supplies a high, local concentration of doxycycline for approximately four weeks. The objective of this post-hoc analysis was to assess the efficacy of D-PLEX$_{100}$ in preventing postoperative soft-tissue infections in patients with 2 or more versus 0-1 SSI risk factors.

Patients and methods

A post hoc analysis of a previously reported prospective randomized trial assessing D-PLEX$_{100}$ plus Standard of Care (SOC) versus SOC alone in colorectal surgery was performed (ClinicalTrials.gov identifier NCT03633123). Two SSI risk groups were compared: $\geq$ 2 risk factors (HIGH); 0-1 risk factors (LOW). Risk factors included: Obesity/Overweight, Diabetes, Hypertension, Peripheral Vascular Disease, and Chronic Obstructive Pulmonary Disease. The standard of care (SOC) regimen included IV antibiotic prophylaxis 30-60 minutes prior to surgery. Patients randomized to the investigational arm received SOC plus D-PLEX$_{100}$ at the time of closure based on the length of surgical incision. SSI rate within 30 days post index surgery between four groups was evaluated: HIGH-SOC; LOW-SOC; HIGH-D-PLEX$_{100}$; LOW-D-PLEX$_{100}$.

Results

The overall incidence of SSI was significantly lower for the D-PLEX$_{100}$ arm (10/101 [9.9%]) versus SOC (21/100 [21%]); p = 0.033. In patients with ≥2 risk factors, SSI incidence was 15/40 (37.5%) for SOC and 6/38 (15.8%) in D-PLEX$_{100}$ treated patients. The LOW-risk groups saw an SSI rate of 17/60 (28.3%) and 9/63 (14.3%) for SOC and treatment arms, respectively. D-PLEX$_{100}$ + SOC significantly reduced SSI incidence in the HIGH-risk factor groups (p=.0415) and approached significance in the LOW-risk factor groups (p=.0769).

Conclusions

D-PLEX$_{100}$ was effective at significantly reducing the incidence of SSIs beyond benefits associated with SOC treatment alone. The data showed advantages in patients with $\geq$2 risk factors, with even the LOW- D-PLEX$_{100}$ group expressing a trend toward reduction in postoperative soft tissue infections. As such, D-PLEX$_{100}$ may be a promising addition to established SSI bundles and is currently being evaluated in several Phase 3 clinical trials (ClinicalTrials.gov Identifier: NCT04411199; NCT04233424; NCT03558984).