

Randomized, multicenter, open label trial.
Patients with diverting ileostomy were randomized to early closure (7-12 days) or late (≥ 8 weeks) ileostomy closure after ileal pouch construction.

Primary endpoints: Comprehensive Complication Index at 30 days after ileostomy closure.

* This trial was stopped after interim analysis because of a high rate of complications after early ileostomy formation

Results:

- Median Comprehensive Complication index 14.8 EARLY vs 0 LATE, $p=0.02$.
- One or more complications occurred in 70% of early closure patients vs 17% in late closure, $p=0.01$
- Severe complications 30% early vs 0% late, $p=0.04$
- Readmission 70% early vs 8% late group, $p=0.003$

Conclusion:

Early closure of a diverting ileostomy in patients with UC who underwent IPAA is associated with an unacceptably high rate of complications.

High Complication Rate After Early Ileostomy Closure: Early Termination Of The Shirt Versus Long Interval To Loop Ileostomy Reversal After Pouch Surgery Randomized Trial

TABLE 2. Diverting loop ileostomy closure and associated postoperative complications

	Early closure (n = 10)	Late closure (n = 12)	p value
Interval to DLI closure, d, median (range)	11 (8–12)	59 (45–182)	< 0.001
DLI closure technique			
Stapled	5 (50)	7 (58)	0.529
Sutured	4 (40)	5 (42)	
DLI closure not achieved	1 (10)	0	
DLI closure operative time, min, median (range)	73 (36–210)	46 (32–189)	0.086
Complications after DLI closure (number of patients)			
Ileus/small-bowel obstruction	5 (50)	2 (17)	0.095
Venous thromboembolism	2 (20)	0	0.104
Enterocutaneous fistula	2 (20)	0	0.104
Bacteremia	1 (10)	0	0.262
IPAA leak	1 (10)	0	0.262
Abdominal fluid collection (ascites)	1 (10)	0	0.262
Acute adrenal insufficiency	1 (10)	0	0.262
Acute kidney insufficiency	0	1 (8)	0.350
Patients with ≥ 1 complication	7 (70)	2 (17)	0.011
1 complication	2/7 (29)	1/2 (50)	
2 complications	3/7 (43)	1/2 (50)	
3 complications	2/7 (29)	0	
≥ 1 severe complication (CD3 or 4)	3 (30)	0	0.041
Comprehensive Complication Index, median (range)	14.8 (0–54)	0 (0–23)	0.020
LOS after DLI closure (index admit), d, median (range)	3.5 (2–25)	2 (1–14)	0.212
Patients with ≥ 1 readmit after DLI closure	7 (70)	1 (8)	0.003
Patients with ≥ 1 reoperation DLI closure	1 (10)	0	0.262

Data are presented as n (%) unless otherwise indicated. Boldface indicates statistical significance at $p < 0.05$.
CD = Clavien-Dindo; DLI = diverting loop ileostomy; LOS = length of stay.

