## Scientific Session VI - Multicenter Trials

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## OUTCOMES AMONG TRAUMA PATIENTS WITH DUODENAL LEAK FOLLOWING PRIMARY VS COMPLEX REPAIR OF DUODENAL INJURIES: AN EAST MULTICENTER TRIAL

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<u>Objectives:</u> Duodenal leak is a feared complication of repair and innovative, complex repairs with adjunctive measures(CRAM) were developed to decrease both leak occurrence and severity when leaks occur. Data on the association of CRAM and duodenal leak is sparse and its impact on duodenal leak outcomes nonexistent. We hypothesized CRAM would 1) be associated with decreased duodenal leak rates and 2) improve recovery and outcomes when leaks do occur.

<u>Methods:</u> A retrospective, multicenter analysis from 35 L1 centers included patients(>14yr) with operative, traumatic duodenal injuries (1/2010-12/2020). The study sample compared duodenal operative repair strategy: primary repair alone(PRA) vs CRAM(any repair plus pyloric exclusion, gastrojejunostomy, triple tube drainage, duodenectomy). Measured study endpoints included duodenal leaks and markers of leak sequelae and recovery.

Results: The sample(n=861) was primarily young(33 years) male(84%) with penetrating injuries(77%); 523 underwent PRA, 338 CRAM. Although CRAM were more critically injured(Table 1) than PRA, CRAM did not correlate with improved leak rates (PRA 8% v CRAM 21%, p<0.001). In turn, adverse outcomes were more common after CRAM with more IR drains, prolonged NPO and LOS, greater mortality, and more 30-day readmissions than PRA(all p<0.05). Importantly, CRAM also had no positive impact on leak recovery(Table 2). There were no differences in number of operations, drain duration, NPO duration, need for IR drainage, HLOS, readmissions or mortality between PRA leak vs CRAM leak patients(all p>0.05). CRAM leaks had longer antibiotic duration, more GI complications and *longer* duration until duodenal leak resolution(all p<0.05).

<u>Conclusions:</u> CRAM did not prevent duodenal leaks and moreover, did not reduce adverse sequelae when leaks did occur. Our results suggest that CRAM is not a protective operative duodenal repair strategy.

Table 1. Clinical variables, entire study sample and duodenal leak subset compared by repair type (PRA vs CRAM)											
	All Patients (n=861)	All Primary Repair Patients (PRA) (n=523)	All Complex Repair Patients (CRAM) (n=338)	p value	All Patients with Duodenal Leaks (n=113)	Duodenal Leaks s/p PRA (n=43)	Duodenal Leaks s/p CRAM (n=70)	p value			
Age (mean ± SD)	33 ± 29	32 ± 14	35 ± 43	0.499	39 ± 72	30 ± 12	44 ± 90	0.418			
Male	84%	83%	85%	0.405	83%	86%	81%	0.524			
Penetrating injury	77%	80%	72%	0.006	81%	88%	77%	0.136			
Systolic Blood Pressure (mmHg)	119 [98–137]	121 [99–138]	114 [96–133]	0.024	113 [94–134]	113 [100–131]	112 [93–135]	0.916			
Injury Severity Score	22 [14-29]	19 [11-29]	25 [16-30]	0.001	24 [16–29]	22 [16–29]	25 [16–29]	0.941			
AIS abdomen	4 [3–4]	4 [3–4]	4 [3-5]	<0.001	4 [3-4]	4 [3-4]	4 [3-4]	0.128			
Massive Transfusion Protocol	39%	35%	46%	0.002	44%	37%	49%	0.193			
Pancreatic injury	32%	25%	43%	<0.001	39%	23%	49%	0.007			
Multiple duodenal Injuries	23%	20%	27%	0.008	34%	35%	33%	0.825			
Duodenal injury AAST grade /	18%	21%	15%	0.022	6%	12%	3%	0.103			
II	40%	50%	24%	<0.001	38%	49%	31%	0.064			
III	34%	28%	44%	<0.001	43%	40%	46%	0.520			
IV	4%	1%	10%	<0.001	10%	0%	16%	0.006			
ν	3%	1%	7%	<0.001	3%	0%	4%	0.287			

Table 1. Clinical variables, entire study sample and duodenal leak subset compared by repair type (PRA vs CRAM)

## PRA = Primary Repair Alone

## CRAM = Complex Repair with Adjunctive Measures

	odenal injury operative management and outcomes, entire study sample and duodenal leak subset compared by repair type (PRA vs CRAM)											
	All Patients with Operative Duodenal Injuries (n=861)	All Primary Repair Patients (PRA) (n=523)	All Complex Repair Patients (CRAM) (n=338)	p value	All Patients with Duodenal Leaks (n=113)	Duodenal Leaks s/p PRA (n=43)	Duodenal Leaks s/p CRAM (n=70)	p value				
Primary Repair Alone (PRA)	61%				38%							
Complex Repairs with Adjunctive Measures (CRAM)	39%				62%			<0.001				
Pyloric Exclusion with Gastrojejunostomy			23%				36%					
Duodenectomy with Enteric Anastomosis			22%				16%					
Duodenal Diverticulization			1%				0%					
Retrograde Duodenostomy Tube and Feeding Jejunostomy Tube			4%				7%					
Whipple			11%				11%					
Combination of complex repairs/Other			39%				30%					
Total Number of Abdominal Operations	2 [1–3]	2 [1–3]	2 [1–4]	<0.001	3 [2-7]	3 [2–5]	4 [2-7]	0.084				
R Drain Placement for Duodenal Leak					42%	35%	46%	0.257				
Duration of drains (days)	12 [6–29]	11 [5–23]	17 [7–67]	<0.001	38 [15–58]	34 [15–43]	43 [16–66]	0.098				
Duration of Antibiotic Therapy (days)					10 [8-21]	9 [7-14]	12 [10-25]	<0.001				
Days until fistula/duodenal leak resolution					14 [4-42]	11 [2–19]	21 [6–58]	0.020				
Days NPO	8 [5–16]	7 [5–13]	11 [6–21]	<0.001	23 [9-48]	23 [8–38]	22 [10-54]	0.575				
GI Related Complication abscess, GI bleed, ulcer, ileus, abdominal compartment syndrome, EC fistula, anastomotic leak)	43%	39%	50%	0.001	81%	65%	91%	0.001				
Hospital Length of Stay (days)	16 [9-30]	14 [8-26]	20 [10-34]	<0.001	38 [22–54]	36 [21–50]	38 [23-48]	0.544				
Mortality	11%	9%	15%	0.002	10%	5%	13%	0.201				
30-day Readmission	20%	17%	23%	0.003	33%	35%	31%	0.879				

Table 2. Duodenal injury operative management and outcomes, entire study sample and duodenal leak subset compared by repair type (PRA vs CRAM)

PRA = Primary Repair Alone

CRAM = Complex Repair with Adjunctive Measures