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Best UEGW Tension trial

OP004 ENDOSCOPIC OR SURGICAL STEP-UP APPROACH FOR NECROTIZING PANCREATITIS, A MULTI-CENTER RANDOMIZED CONTROLLED TRIAL S. Van Brunschot AMC

- Infected necrotizing pancreatitis is a potentially lethal disease that almost always requires an invasive intervention. In recent years, the surgical step up approach has become standard of care replacing primary open necrosectomy.
- A promising minimally invasive alternative is the endoscopic step-up approach.
- We conducted a multicenter randomized trial (TENSION trial) comparing a endoscopic and surgical step-up approach in patients with infected necrotizing pancreatitis.

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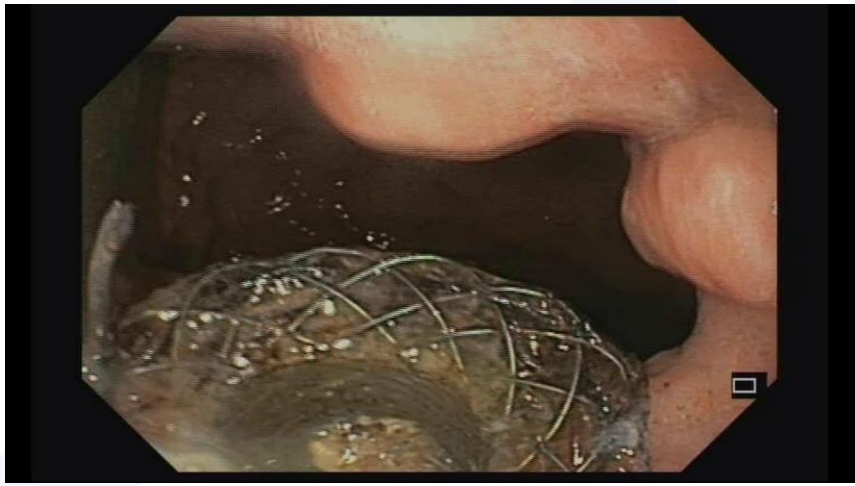
- Aims & Methods:
  - Prospective randomization
  - The endoscopic step-up approach consisted of endoscopic transluminal drainage followed, if necessary, by endoscopic necrosectomy.
  - The surgical step-up approach consisted of percutaneous catheter drainage followed, if necessary, by video-assisted retroperitoneal debridement (VARD).
  - The primary endpoint was a composite of major complications (i.e. new onset organ failure, bleeding, perforation of a visceral organ, enterocutaneous fistula and incisional hernia) or death during 6 months of follow-up.
  - Secondary endpoints included, among other, pancreatic fistula, length of hospital stay and costs.



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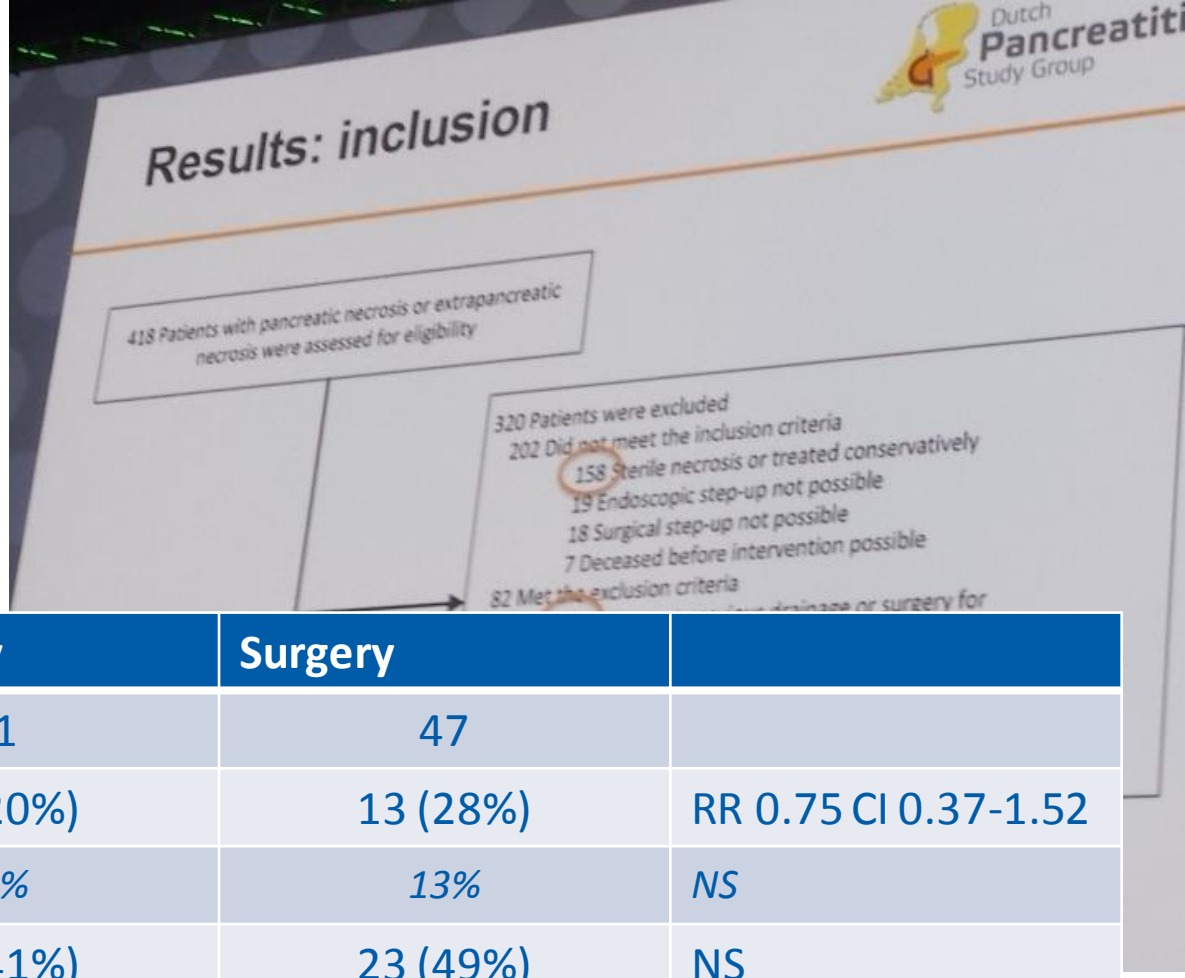
A total of 98 patients were enrolled in 19 Dutch hospitals



	Endoscopy	Surgery	
n	51	47	
Primary endpoint	10 (20%)	13 (28%)	RR 0.75 CI 0.37-1.52
Death	*18%*	*13%*	*NS*
NO Necrosectomy	21 (41%)	23 (49%)	NS
Fistula	5%	32%	P<0.001
LOS	36d	69d	P: 0.03
Cost	660228	673883	Diff 13655€

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Conclusion:

The TENSION trial did not show superiority of the endoscopic stepup approach, as compared with a surgical step-up approach, in reducing major complications or death in patients with infected necrotizing pancreatitis.

However, the rate of pancreatic fistula, length of hospital stay and costs were significantly reduced in the endoscopic group.

NSAIDS and PEP

OP114 RECTAL INDOMETHACIN MAY NOT DECREASE THE INCIDENCE OF POST-ERCP PANCREATITIS IN CONSECUTIVE PATIENTS: A META-ANALYSIS OF RANDOMIZED AND CONTROLLED TRIALS Shyam Varadarajulu and Rob Hawes

Introduction: Data on the efficacy of prophylactic rectal indomethacin to prevent post-ERCP pancreatitis in consecutive patients is inconsistent.

We therefore conducted a meta-analysis of high-quality RCT specifically studying rectal indomethacin in prevention of PEPs in consecutive patients.

Aims & Methods: Relevant studies for the meta-analysis were identified through search of MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials databases. Randomized controlled clinical trials employing rectal indomethacin for the prevention of post-ERCP pancreatitis were included.

The primary outcome was the overall rates of PEP

Characteristics of Included Trials

	Montano Loza, 2007	Sotoudehmanesh, 2007	Dobronte, 2012	Dobronte, 2014	Patai, 2015	Levenick, 2016
Methodology						
Intervention	100 mg PR before ERCP	100 mg PR before ERCP	100 mg PR before ERCP	100 mg PR before ERCP	100 mg PR before ERCP	100 mg PR during ERCP
Location	Mexico-multicenter	Iran-single center	Hungary-single center	Hungary-multicenter	Hungary-single center	US-single center
Definition of post-ERCP pancreatitis	Clinical, amylase	Clinical, amylase	Pain, amylase, pro-longed admission	Clinical, amylase, pro-longed admission	Pain, amylase, pro-longed admission	Pain, amylase, pro-longed admission
Pancreatic stent used?	Yes (10 cases in indo-methacin group; 9 cases in placebo group)	No	N/A	No	No	Yes (36 cases in indo-methacin group; 35 cases in placebo group)
Randomization						
Total randomized	150	490	228	686	539	449
Total analysed	150	442	228	665	539	449
Indomethacin	75	221	130	347	270	223
Placebo	75	221	98	318	269	226
Baseline demographics						
Mean age (y)						
Indomethacin	55	58	66	66	66	65
Placebo	51	58	67	68	65	64
% Female						
Indomethacin	65	56	63	62	67	53
Placebo	68	53	70	67	67	52
Procedure demographics						
% Difficult cannulation						
Indomethacin	N/A	N/A	N/A	18	29	21
Placebo	N/A	N/A	N/A	16	30	19
% Pancreatic duct injection						
Indomethacin	7	20	63	71	23	22
Placebo	8	19	68	68	30	22

NSAIDS and PEP
Results

- Results: 2473 patients from 6 studies were included
  - Incidence of PEP 7% (95% CI, 6%–9%)
  - no significant difference in overall rates of PEP in consecutive patients between rectal indomethacin and placebo (OR, 0.67; 95% CI, 0.46–1.00, p¼0.050).
  - no difference in rates of moderate to severe (OR, 0.66; 95% CI, 0.28–1.56, p¼0.345) or mild (OR, 0.71; 95% CI, 0.45–1.10, p¼0.127)

Conclusion: In a contemporary meta-analysis of available randomized controlled trials of consecutive patients undergoing ERCP, rectal indomethacin did not show significant prevention effect of post-ERCP pancreatitis.

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CLINICAL—PANCREAS

Rectal Indomethacin Does Not Prevent Post-ERCP Pancreatitis in Consecutive Patients

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Table 3. Exploratory Subgroup Analysis of Patients With Post-ERCP Pancreatitis

	Patients with PEP		
	Indomethacin (n = 16)	Placebo (n = 11)	Relative risk reduction (indomethacin vs placebo), %
Pancreatic stent placement, n (%)	8 (50)	4 (36)	−28
Suspected sphincter of Oddi dysfunction, n (%)	1 (6)	1 (9)	+33
History of post-ERCP pancreatitis	2 (13)	1 (9)	−21
Difficult cannulation	6 (38)	5 (45)	+16
Wire cannulation of pancreatic duct, n (%)	13 (81)	7 (64)	−21
Pancreatography, n (%)	8 (50)	8 (73)	+32
Pancreatic acinarization, n (%)	2 (13)	0 (0)	NA
Therapeutic biliary sphincterotomy, n (%)	7 (44)	3 (27)	−39
Therapeutic pancreatic sphincterotomy, n (%)	2 (13)	3 (27)	+52
Balloon dilation of biliary sphincter, n (%)	0 (0)	1 (9)	NA
Trainee involvement in ERCP, n (%)	12 (75)	8 (73)	−3