

USE OF RELOADABLE CLIPS DURING PER-ORAL ENDOSCOPIC MYOTOMY (POEM) IS SAFE, EFFECTIVE, AND COST EFFECTIVE

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BACKGROUND

- Endoscopic clip closure is routinely used in Per-Oral Endoscopic Myotomy (POEM).
- POEM is a safe and effective procedure for achalasia patients (pts) when the endoscopist is properly trained.
- Clip use can be costly and our large volume tertiary center has seen a rise in clip utilization overall.
- Continued POEM evolution will lead to improved outcomes and increased cost-effectiveness.

AIMS

- We aim to evaluate the performance and cost effectiveness of implementing the newly available (in USA) Reloadable Clips (RC) in addition to standard, Single-use clips (SC) during tunnel closure in POEM.

METHODS

- A retrospective cohort study of consecutive pts undergoing POEM for achalasia (before/after introduction of RC) was undertaken.
- Pt demographics, disease/treatment characteristics were recorded.
- POEM was performed by a single-trained Advanced Interventional Endoscopist with standardized protocol.
- All pts were admitted to observation with barium esophagram within 12 hours of POEM.
- Treatment efficacy was measured by immediate technical success, absence of leak on esophagram, and symptom evaluation at follow-up.
- Treatment related adverse events recorded were dysphagia, bleeding requiring transfusion, leak on esophagram, ED visit, and emergency operation.
- Procedural details of incision length, anterior/posterior approach, type of incision, myotomy length, and number and type of clips (RC vs SC - (Figure 1)) used for zipper closure technique were noted.
- Cost of clips used per case was calculated.
- Statistical analysis with Fisher's exact and two-tailed unpaired T test was performed.

	(RC + SC) Group 1 (n=14)	(SC) Only Group 2 (n=10)	P value
Achalasia Type			
1	4/14 (29%)	2/10 (20%)	P = 1*
2	7/14 (50%)	7/10 (70%)	P = 0.42*
3	3/14 (21%)	1/10 (10%)	P = 0.61*
Mean Incision Length			
2 - 2.5cm	11/14 (79%)	9/10 (90%)	P = 0.61*
3.5cm	3/14 (21%)	1/10 (10%)	
Location of Incision			
Anterior	3/14 (21%)	3/10 (30%)	P = 0.66*
Posterior	11/14 (79%)	7/10 (70%)	P = 0.67*
Type of Incision			
Circular	9/14 (64%)	8/10 (80%)	P = 0.65*
Full Thickness	5/14 (36%)	2/10 (20%)	P = 0.65*
Mean Myotomy Length (cm)	8.7 ± 2.3	7.3 ± 1.2	P = 0.08^
Mean Number of Clips per case			
Total	6.4 ± 1	5.7 ± 1.2	P = 0.15^
Reloadable Clips (RC)	3 ± 2.7	0	
Standard, single use Clips (SC)	1.3 ± 0.5	5.7 ± 1.2	
Mean Total Clip Cost (\$)	454	855	P = 0.0001^
Early Treatment Related Adverse Events			
Leak on esophagram	0/14 (0%)	0/10 (0%)	P = 1*
Delayed Treatment Related Adverse Events			
Dysphagia	0/14 (0%)	1/10 (10%)	P = 0.42
Pain	1/14 (7%)	1/10 (10%)	P = 1
Fever	0/14 (0%)	0/10 (0%)	P = 1

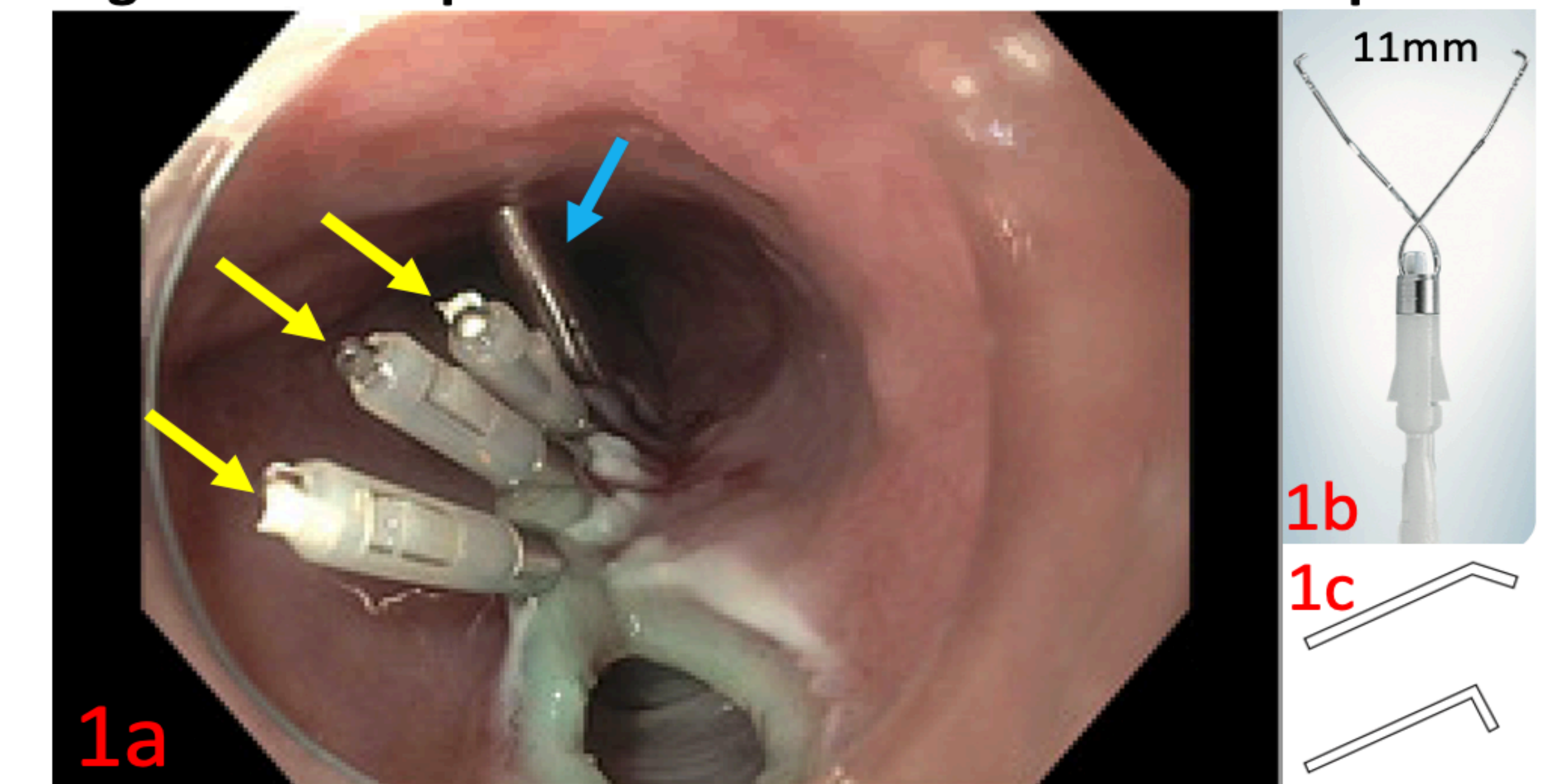
*Fisher's Exact test

^Two-tailed, unpaired T test

RESULTS

- 24 achalasia pts (Table 1) were evaluated.
- 14/24 (58%) patients were in Group 1 (RC+SC) and 10/24 (42%) were in Group 2 (SC only).
- 24/24 patients had immediate technical success and no early treatment related adverse events.
- Mean total number of clips/case in Group 1 (6.4 ± 1) and Group 2 (5.7 ± 1.1) did not differ (p=0.15).
- Mean myotomy length in Group 1 vs Group 2 was (8.7cm vs 7.3cm, p=0.08).
- Cost for RC was \$100.50 for 1st clip, \$39.50 for 2nd clip, and \$39.50 for each subsequent clip.
- The cost for each SC was \$150.
- Mean total clip cost per case in Group 1 was \$454 compared to \$855 for Group 2 (p<0.001).

Figure 1: Examples of Reloadable and Standard Clips



Zipper closure technique (figure 1a); RC clip (yellow arrows, figure 1a); SC clip (blue arrow, figure 1a); opening width of RC (figure 1b), 135-degree jaw of RC (top of figure 1c)

CONCLUSION

- Use of RC in POEM was safe, technically successful, and highly cost effective.
- RC can be used alongside SC for zipper closure technique.
- Further prospective studies evaluating their use in EMR/ESD may lead to similar cost savings.