

Low Volume Preparation Regimen for Colon Capsule Endoscopy – Clinical Study

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CONCLUSIONS

Plenvu[®]/SuPrep[®]/Resolor[®] achieved superior completion when compared to a high-volume preparation regimen; however, the AE results were not inferior.

Plenvu[®]/SuPrep[®]/Resolor[®] may be an alternative low volume preparation regime for CCE procedures.

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Disclaimer

This poster presents an alternative preparation regimen that is different from the preparation regimen used in the study that determined the accuracy of PillCam[™] COLON 2 as presented in the labeling.

References

- Eliakim R et al. Endoscopy. 2006 Oct;38(10):963-70.
- Van Gossum et al. Erratum in: N Engl J Med. 2009 Sep 17;361(12):1220.
- Rex et al. Gastroenterology. 2015; 148: 948-957.
- Leighton et al. 2011; 43: 123-127.

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Table 1. Description of the preparation regimens

	Low Volume Preparation Regimen				High Volume Preparation Regimen		
	Time		Plenvu [®] /SuPrep [®] /Resolor [®]	SuPrep [®] /Pico-Salax [®] /Resolor [®]	Time		Historical Control (high volume)
Day -2	All day	Clear liquids	At least 10 glasses	At least 10 glasses	All day	Clear liquids	At least 10 glasses
	Evening	Senna tablets	40mg (2x20mg)	40mg (2x20mg)	Bedtime	Senna tablets	4 tablets (12 mg)
Day -1	All Day	Clear liquids diet			All day	Clear liquids diet	
	20:30-22:00	Evening prep	0.5L Plenvu [®]	0.5L SuPrep [®]	19:00-21:00	Evening prep	2 liters of PEG (SF-ELS) solution
Day 0	07:00 - 07:30	Morning prep	0.5L Plenvu [®]	0.5L SuPrep [®]	07:00-08:30	Morning prep	2 liters of PEG (SF-ELS) solution
	07:30 - 08:30	Clear liquids	1L Clear liquids	1L Clear liquids	09:15	PillCam [™]	PillCam [™] COLON 2
	08:30	Tablet	Resolor ^{®**} , 2mg	Resolor ^{®**} , 2mg	10:00 - 10:30 *	Boost 1 (G2SB)	0.5L SuPrep [®]
	09:15 (up to 09:45)	PillCam [™]	PillCam [™] COLON 2	PillCam [™] COLON 2	10:30 - 11:30	Clear liquids	1L Clear liquids
	10:00 - 10:30 *	Boost 1 (G2SB)	0.5L SuPrep [®]	0.15L Pico-Salax [®]	13:00 - 13:15	Boost 2 (3 hours after Boost 1)	0.25L SuPrep [®]
	10:30 - 11:30	Clear liquids	1L Clear liquids	1L Clear liquids	13:15 - 13:45	Clear liquids	1L Clear liquids
	12:00 - 12:15	Boost 2 (2 hours after Boost 1)	0.25LSuPrep [®]	0.075L Pico-Salax [®]	15:00 - 15:15	Suppository (2 hours after Boost 2)	10 mg bisacodyl
	12:15 - 12:45	Clear liquids	0.5L Clear liquids	0.5L Clear liquids	17:00	Light meal (2 hours after Suppository)	
	14:00 - 14:15	Boost 3 (2 hours after Boost 2)	0.25LSuPrep [®]	0.075L Pico-Salax [®]			
	14:15 - 14:45	Clear liquids	0.5 Clear liquids	0.5L Clear liquids			
	15:00	Light meal (1 hour after Boost 3)					
16:00	Suppository (1 hour after the meal)	10 mg bisacodyl	10 mg bisacodyl				
MAXIMUM SOLUTION VOLUME			2L	1.3L	4.75L		

* Time of capsule passage into small bowel (G2SB) is estimated. 10mg Reglan[®] is administrated in case the capsule fails to enter SB within 1h from ingestion (alert 0).

** Resolor[®] is the specific brand of prucalopride that was used.

INTRODUCTION

- Colon capsule endoscopy (CCE) allows a minimally invasive colonic investigation without requiring sedation, endoscopic intubation or air insufflation¹.
- CCE needs adequate bowel preparation to clean the colon in order to optimize mucosal visualization² and promote capsule propulsion through the colon.
- Bowel preparation regimen remains a significant barrier for patients who must consume a high-volume preparation regimen.
- The aim of this study was to investigate the non-inferiority of two low-volume preparation regimens compared to a high-volume preparation regimen.

METHODS

- Two new low-volume preparation regimens were investigated (Table 1) in healthy participants (age 50+):
 - Plenvu[®]/SuPrep[®]/Resolor[®] (n=101)
 - SuPrep[®]/Pico-Salax[®]/Resolor[®] (n=99)
- For the historical control (HC) group, a subset of 142 subjects (age 50+) received a high-volume regimen (Table 1) from a previously published diagnostic study³.
- All regimens were reviewed by the same experienced CCE reader.
- The endpoints for this study were overall adequate cleansing, capsule excretion rate in 10 hours, completion and adverse events (AEs).

RESULTS

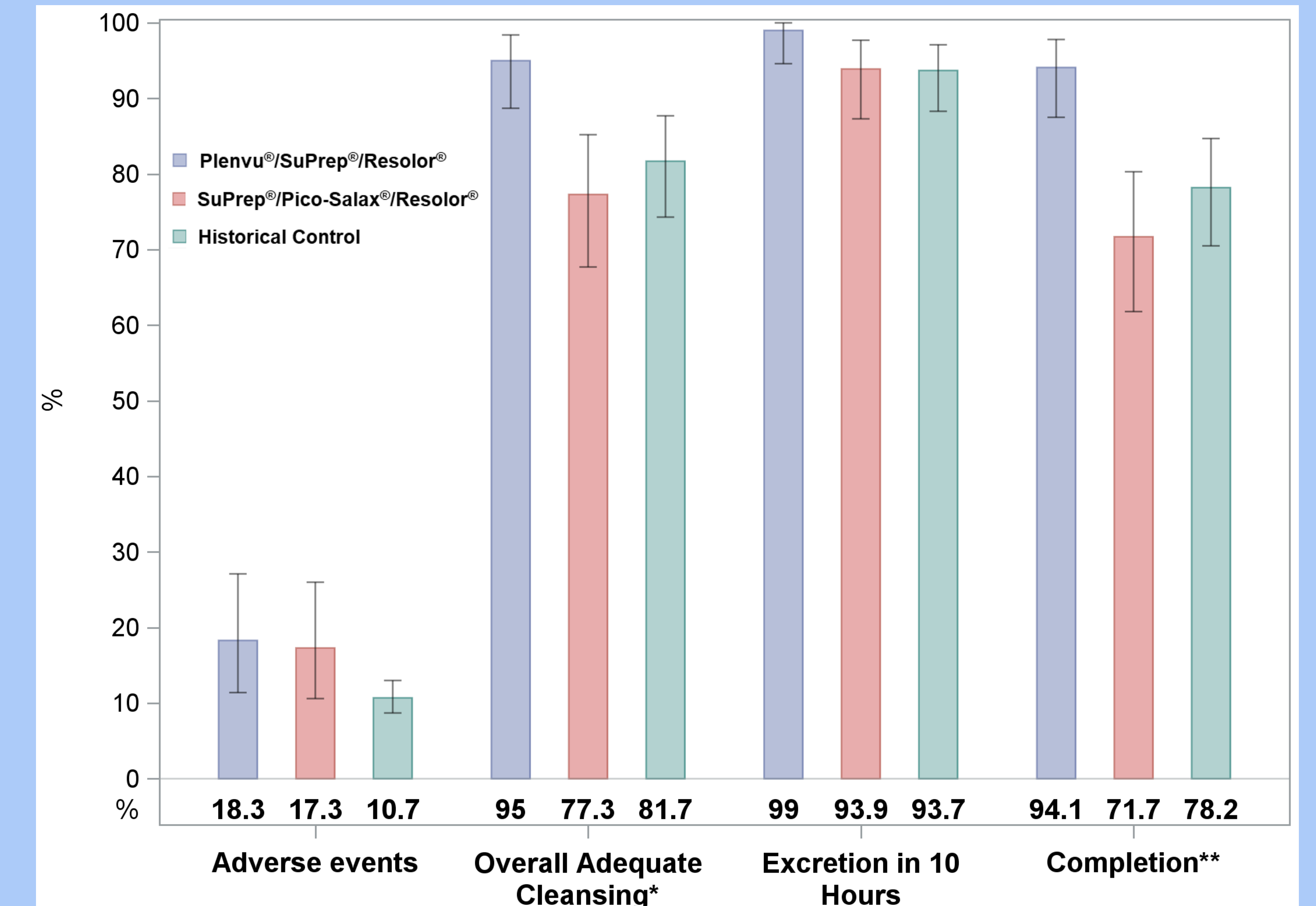
Plenvu[®]/SuPrep[®]/Resolor[®] vs. HC

- Plenvu[®]/SuPrep[®]/Resolor[®] group demonstrated superior results with regard to colon cleansing and completion (P<0.0001) and was non-inferior with regard to capsule excretion in 10 hours (P<0.0001).
- Non-inferiority was not established for AEs (P=0.045) as Plenvu[®]/SuPrep[®]/Resolor[®] group demonstrated a higher rate of AEs, which were primarily mild vomiting.

SuPrep[®]/Pico-Salax[®]/Resolor[®] vs HC

- SuPrep[®]/Pico-Salax[®]/Resolor[®] group demonstrated non-inferior results with regard to capsule excretion in 10 hours (P=0.0002), cleansing (P=0.028) and AE (P=0.027).
- Non-inferiority for completion was not established (P=0.07).

Figure 1. Study endpoints rate by regimen



*Overall adequate cleansing according to the Leighton and Rex cleansing scale⁴
**Completion = Overall adequate cleansing and excretion in 10 hours