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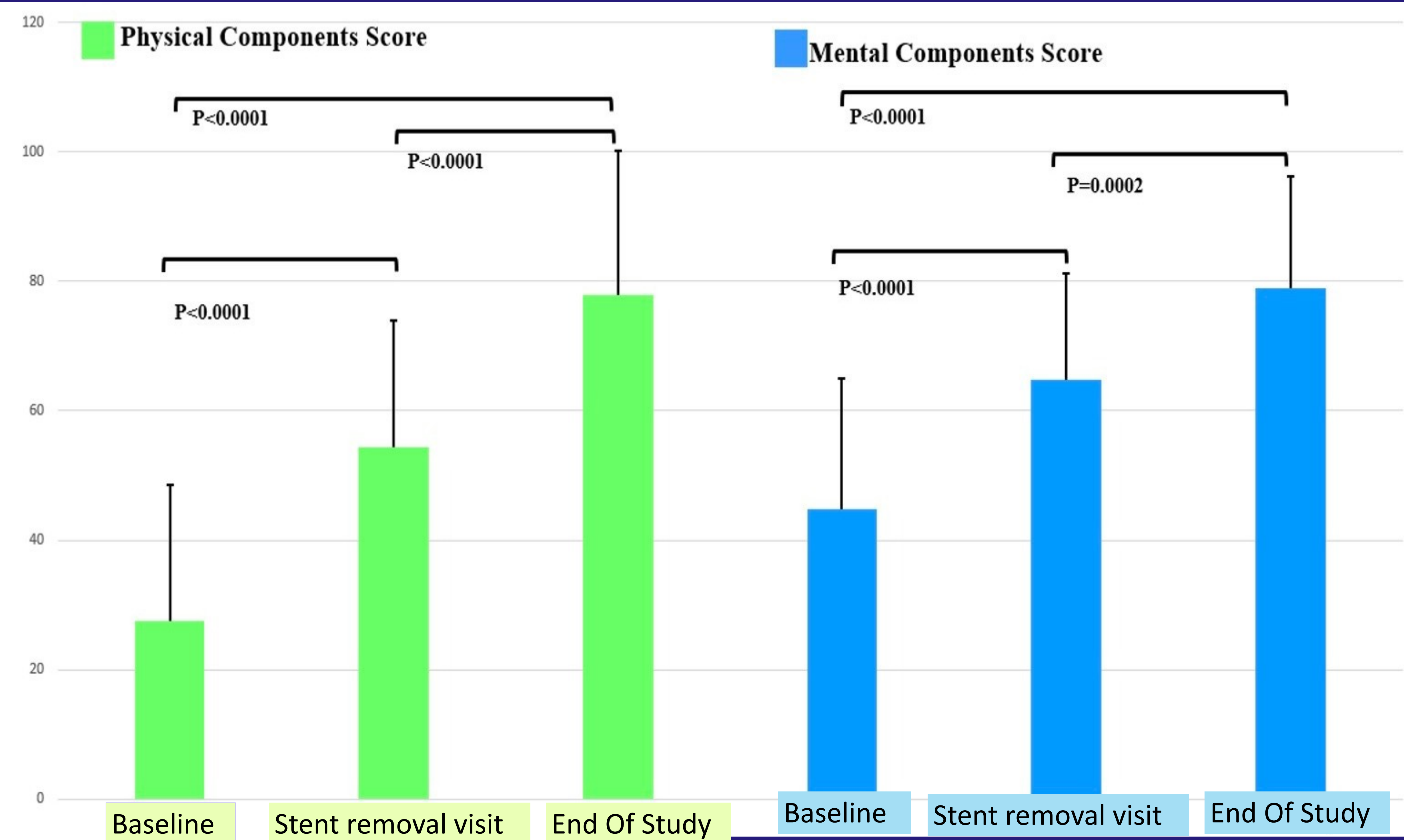
# Assessment of Physical and Mental Health Before and After Protocolized Endoscopic Necrosectomy for Walled-Off Pancreatic Necrosis in a Prospective Multi-Center Trial

## INTRODUCTION

- A regulatory FDA IDE prospective multi-center clinical trial (G170261-NCT03525808) was performed to evaluate rigorous protocolized management of walled off necrosis (WON)  $\geq 6$  cm in size with  $> 30\%$  necrotic material using endoscopic ultrasound (EUS) guided lumen apposing metal stent (LAMS) placement with/without endoscopic necrosectomy.
- Few studies have examined changes in health related quality of life (HRQOL) before and after endoscopic management for WON.
- The SF-12 is a validated measure of HRQOL containing 12 items which yield a Mental Components Score (MCS) and a Physical Components Score (PCS). Higher scores correspond to a greater perceived quality of life.

## METHOD

- The pre-specified target sample of 40 patients was enrolled by multiple centers from Sept 2018 to Mar 2020.



- Patients with radiographic WON resolution (as demonstrated by size  $\leq 3$  cm on CT or MRI) and/or 60 days LAMS indwell time had stent removal followed by an end of study visit 6 months later.
- SF-12 quality of life questionnaires were completed by patients at baseline, stent removal and at the end of study visit.

## RESULT

- Mean SF-12 Physical Components Score (PCS) was 27.5 ± 21.1 at baseline, 54.4 ± 19.5 at the time of LAMS removal, and 77.9 ± 22.3 at end of study.

Figure 1: SF-12 Physical and Mental Components Score

- Mean SF-12 Mental Components Score (MCS) was 44.9 ± 20.1 at baseline, 64.7 ± 16.5 at the time of LAMS removal, and 79.0 ± 17.2 at end of study.
- The mean improvement in PCS score from baseline to LAMS removal was 26.0 ± 24.8 ( $p < 0.0001$ )
- The mean improvement in PCS score from baseline to end of the study was 49.1 ± 29.6 ( $p < 0.0001$ ).

- The mean improvement in MCS was 19.6 ± 20.1 from baseline to LAMS removal ( $p < 0.0001$ )
- While the mean improvement in MCS was 32.0 ± 22.3 from baseline to the end of study ( $p < 0.0001$ ).
- The mean improvement from the time of stent removal to the end of study was 25.2 ± 18.0 (PCS,  $p < 0.0001$ ) and 15.5 ± 18.5 (MCS,  $p = 0.0002$ ) (Figure 1).

## Conclusion

- These data suggest that patients undergoing protocolized endoscopic necrosectomy for walled-off pancreatic necrosis experience significant improvement in both physical and mental HRQOL.
- Improvement in the physical score domain appeared to be greater than for the mental score domain.
- HRQOL indicators continued to improve over a mean follow-up of 180 days.