

# Review on Laghu Shankha Prakshalana/ Shankha Prakshalana: A Safe and Effective Yogic Technique for Hypertension, Obesity, Constipation, Back Pain, and Irritable Bowel Syndrome by Targeting Bowel

Rupesh Kumar<sup>1</sup>, Swati Kumari<sup>2</sup>

<sup>1</sup>Assistant Professor, Department of Yogic art and Science, Visva Bharti University, West Bengal, India  
Corresponding Author Email: [rupeshkumaryogi2662\[at\]gmail.com](mailto:rupeshkumaryogi2662[at]gmail.com)  
Contact - 7015305955

<sup>2</sup>Ph. D. Scholar, Interdisciplinary Centre for Swami Vivekananda Studies, Panjab University, Chandigarh, India

**Abstract:** ***Objective:** Laghu Shankha Prakshalana/ Shankha prakshalana (LSP/SP) is a yogic way that corrects altered bowel habits. Bowel health plays a vital role in physical and psychological health as its association with the cardiovascular system, liver, kidney, unspecific pain, and psychological health (gut - brain axis), is well known. Local inflammation, dysbiosis, altered bowel habits, and hypersensitivity can play a role in the manifestation or worsening of other diseases. So, targeting the bowel can be a treatment strategy for many other diseases. The review aims to establish the evidence for LSP/SP targeting the bowel as a treatment option for different health - related problems. **Method:** A systematic search on PubMed, Embase, and Google scholar by the keywords “Laghu shankha prakshalana”, “Shankha Prakshalana” and “Varisaradhauti” was done by three authors. A total of 12 studies came out were only 6 satisfied the inclusion criteria and were included in the study. Outcomes were not pre - decided as all the areas where LSP/SP contributed individually were aimed to study. **Result:** The review shows that LSP/SP has been administered safely to healthy individuals and patients with constipation, irritable bowel syndrome, early cases of renal failure, Chronic low back pain, hypertension, and obesity. Significant statistical changes in all the outcomes reporting are safe, are enthusiastic. **Conclusion:** LSP/SP is a safe and effective technique for bowel cleansing. Strong evidence is lacking because of inadequate sample size and randomization in some studies but the enthusiastic results open a way for the researchers to work on LSP/SP.*

**Keywords:** Yoga, Bowel, Laghu shankha prakshalana, Constipation, Irritable bowel syndrome, hypertension, lipid, Safety

## 1. Introduction

Yoga, being a part of ancient Indian culture, is developing as an alternative therapy system nowadays. Asana (Physical Posture), Pranayama (Breathing exercise), and Dhyana (Meditation) are mainly considered in recent interventional studies, which are parts of Hatha Yoga, a tradition of yoga<sup>1</sup>. Many clinical trials reported the effectiveness of the yogic interventions on the physiological and psychological outcomes based on these three practices. However, the tradition focuses on internal cleansing also described as *shatkarmaorkriya*<sup>2</sup>. These are powerful practices that create harmony between mind and body resulting in the revitalization and rejuvenation of the body with good physiological effects<sup>3</sup>. Among the several types of *kriyas*, *varisaradhauti* (*shankhaprakshalana*) the one from *antahdhauti* mentioned in *Gherand Samhita*, is a technique to clean the entire alimentary canal followed by a specific module<sup>4</sup>. Laghu shankha prakshalana is a short version of Shankha Prakshalana which is intended to promote the normal functioning of the intestines<sup>5</sup>. The five most common asanas can be performed each (exercises) eight times are: Tadasana, Tiryaka Tadasana, Katichakrasana, Tiryaka Bhujangasana, and Udarakarshanasana. Hence, the review is focused primarily on Shankha Prakshalana/Laghu Shankha Prakshalana (LSP) as a yogic intervention in the studies.

The main objective of this review is to see the various approaches of *Shankha prakshalana/ Laghu Shankha Prakshalana* (LSP) on different health - related outcomes among healthy or unhealthy individuals. The scope of the study maybe to provide evidence of *Shankha prakshalana/ Laghu Shankha Prakshalana* (LSP) as a therapy option in various health disorders.

## 2. Literature Search Methodology

For this review, we mainly searched, synthesized, and cataloged data in PubMed, Google Scholar, and Embase. Additionally, we used secondary sources of data by manually assessing the relevancy of the internet and traditional literature. We used a variety of keywords and their combinations to optimize the search because the theme of the research review encompasses various points of view. These keywords included, in order of relevance: “Laghu Shankha Prakshalana”, “Shankha Prakshalana” and “Varisara Dhauti”. The search results were manually examined and evaluated in order to concisely shape the review.

**Evidence of laghu shankha prakshalana/ Shankha prakshalana (LSP/SP) for (Figure 1):**



### Safety and effectiveness in hypertension

Hypertension is a medical condition in which the blood pressure against the wall of arteries remains higher than the normal limit of 120/80mmHg. Due to less awareness and control, it has been reported with high prevalence in different parts of India<sup>5</sup>. According to National Family Health Survey (NFHS - 4) in 2014 - 15, the prevalence of hypertension was found to be 18.1% (95% CI, 17.8%–18.4%) in the age group of 18 - 49 years<sup>6</sup>. Persistent increased blood pressure can be the risk factor for life-threatening health conditions like heart disease, CAD (coronary artery disease), CHD (coronary heart disease), aortic aneurysms, kidney disease, vascular dementia, heart attacks, strokes, heart failure, peripheral arterial disease, as reported by the biggest health website of the UK, National Health Service (NHS)<sup>7</sup>. A systematic review and meta-analysis on behalf of 13 studies, concluded *yoga and Meditation* to be useful alternatives to pharmacotherapy<sup>8</sup>. Apart from a sedentary lifestyle, being overweight, high salt consumption, stress, and other factors, the role of dysfunctional sympathetic-gut communication associated with dysbiosis, gut pathology, and inflammation is also known<sup>9</sup>. Earlier it was understood that the practice of LSP may not be safe for hypertensive patients. Mashyal et al<sup>10</sup>. examined the safety and effectiveness of *Laghu Shankha Prakshalana* in patients with essential hypertension (mild to moderate) in a single - armed study. 32 patients (male and female) went through a week - long Integrated Approach of Yoga Therapy (IAYT) module comprising LSP and other yogic practices (LSP+Y) at Bengaluru, Karnataka. Blood pressure was measured before and after LSP on the 1<sup>st</sup> (without *Triphala*) and 6<sup>th</sup> day (with *Triphala*). The systolic blood pressure decreased from 137.25±16.3 to 127.81±12.8 after the normal water LSP (NWLSP) session and from 141.8±19.2 to 125.5±13.9 after LSP with Triphala water (TWLSP) at p<0.001; diastolic blood pressure decreased from 86.43±9.47 to 80.68±8.0 after NWLSP and from 87.5±10.15 to 78.40±8.2 after TWLSP session at p<0.001. However other yogic practices were also included with LSP but those were controlled in all the patients and just before and after the results of LSP are discussed here. However, the control group could make the study more reliable yet LSP is safe in mild to moderate essential hypertension patients and LSP with *Triphala* provided better results in reducing blood pressure. Practicing LSP once a week for a longer time duration may give better and more stable results in hypertension.

### Safety in healthy individuals:

The concept of colon cleansing is often considered to be associated with some side effects like dehydration, infection, and electrolyte imbalance, which can be dangerous for kidney, heart disease, or other health problems<sup>11</sup>. Many studies have proved its safety and effectiveness among different patient populations. But it is recommended to practice it under the surveillance of a qualified experienced yoga therapist. Kumar et al.<sup>12</sup> investigated the immediate effect of LSP on 40 subjects aged 18 - 25 in Haridwar, Uttarakhand. Body weight, temperature, pulse rate, and blood pressure were accessed in the pre - post analysis of a single session. The change in blood pressure from 108.8±3.84 to 108.9±3.71 was reported with no significant reduction. Body weight, temperature, and pulse rate also did not show any significant reduction. The study suggests that LSP is safe for healthy individuals as the changes did not vary too much. It increased the motility of the gastrointestinal tract which can be immediately influential to digestion, absorption, and assimilation. Study reveals that LSP can be practiced safely by healthy persons without any side effect. However, the concept of LSP is slightly different as it is done with lukewarm saline water which increases the peristalsis of the intestines and creates propulsive motility<sup>13</sup>.

### Effectiveness in Constipation:

Constipation is a bowel problem linked with less frequency or difficulty in passing stool. Criteria to diagnose constipation vary according to the region. A study by Gautam ray et. al<sup>14</sup> concluded <5 motions/week seems to be an appropriate definition for constipation where at least 1 motion per day is considered to be a healthy bowel habit. Constipation is associated with reduced quality of life and work productivity. In *Ayurveda* purgation (*virechana*) can be used for constipation (*bandha*) which eliminates pitta<sup>15</sup>. LSP is very similar to *virechana* as it increases bowel motility and cleanses the bowel. Kiran et al.<sup>16</sup> evaluated the safety and the effect of LSP on bowel health among 60 healthy subjects randomized into two groups of 30 subjects to each group. The study arm went through the procedure of LSP once a week, continuously for 4 weeks whereas the control arm received no intervention. A significant reduction in Constipation Scores (measured by Cleveland Clinic CS) from 8.73±0.69 to 3.63±0.49 was found in the study arm at p < 0.001 whereas the control group demonstrated no statistically significant difference between the group. No adverse event or effect was found during the 4 - week study duration. It can be concluded that LSP is safe and effective for patients with constipation.

### Effectiveness in Irritable Bowel Syndrome and early cases of renal failure:

Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder with a high prevalence of 9.6% in Asian countries<sup>17</sup>. Low - grade mucosal inflammation, impaired gut motility, altered gut - microbiome, hypersensitivity, and dietary influence are associated with the pathophysiology of IBS which is often seen in the link with dyspepsia, dysphagia, non - cardiac chest pain, and nausea<sup>18</sup>. LSP can be a good alternative to treat bowel health as it eliminates all toxins from the stomach and cleans the whole alimentary canal<sup>19</sup>. Singh et al.<sup>20</sup> used *shankha prakshalana* on different patients of irritable bowel syndrome (IBS), anxiety neurosis, chronic renal failure, thyrotoxicosis, and healthy volunteers. The study mainly revealed the qualitative analysis only. Among 27 patients of IBS, a significant relief of 85.71% in subjects with constipation, 87.37% in abdominal pain, 42.85% in irregular bowel habits, and 50.00% in diarrhea cases was reported. In the same patient population, 40% of patients noticed increased appetite, 33% of them relieved from vomiting tendency and 57.14% reported reduced drug dependency. Apart from all these, 2 early cases of renal failure showed a drastic reduction in blood urea levels from 163 mg% and 215 mg% to 32 mg% and 38 mg% respectively after three weeks. However other qualitative results were also reported from healthy volunteers (12), anxiety (17 patients), and thyrotoxicosis (5 patients), which showed "satisfactory result", "symptomatic relief" and "general feeling of well - being" respectively, as an output.

### Evidence of the effectiveness in chronic low back pain

Low back pain also known as Lumbago is one the very common problems involving the muscles, bones, and nerves. All of us must face once Prevalence of Chronic low back pain has been administered 19.6% worldwide in the age group of 20 - 59 years<sup>21</sup>. A significant and positive association is seen between constipation and lower back pain<sup>22</sup>. People with a highly sedentary lifestyle and less physical activity are prone to constipation. Many other factors may be linked with the pain but targeting the bowel can be an option for treatment. Ayurveda suggests *mriduvirechana* for *Vata* disorders such as *Katishoola* (low back pain)<sup>23</sup>, where medicated drugs are given to the patients to pass loose stools<sup>24</sup>. LSP is also very similar to *mriduvirechana* as it creates purgative sensations and cleanses the bowel. In a cross - over randomized controlled trial by Haldavnekar et. al<sup>25</sup>, the immediate effect of LSP was assessed on the patients with chronic low back pain. Forty pat of age group 25 - 70 years were randomly assigned to either group A for LSP or group B for back pain - specific asana/technique (BST) on 3<sup>rd</sup> day. Patients of Groups A and B were interchanged on the 5<sup>th</sup> day. Pain intensity by Oswestry disability index (ODI) and Eleven - point numerical rating scale, spinal mobility by Leighton type goniometer, trait anxiety by Spielberger's state and trait anxiety inventory, and spinal flexion by Straight leg raising test, were measured before and after the intervention on both the days. A significant reduction from 2.70±1.54 to 1.70±1.47 in ODI scores and from 5.35±2.00 to 4.03±1.8 in 11 points numerical rating scale was reported at p<0.001. A significant reduction in state anxiety and spinal flexibility

was also reported to be statistically significant. There was a significantly ( $P < 0.001$ , between groups) better reduction in LSP than the BST group on all variables. Any kind of adverse effects were not reported by any participant.

### Effectiveness in lipid profile

Around 135 million people are obese in India which is caused by the regular consumption of high calorie food, less workout, fewer health care services, and financial problem<sup>26</sup>. The association among dyslipidemia, obesity, and hypertension is well known which are found to be the risk factors for cardiovascular disease<sup>27</sup>. Obesity greatly increases the risk for chronic diseases like CAD, Ischemic Heart disease, type 2 diabetes, low back pain, cardiovascular disease, certain cancer.<sup>28</sup>. Yoga has been reported<sup>29</sup> as a safe technique to reduce BMI and waist circumference among women but a treatment directly targeting the internal organs may be more effective. LSP can reduce cholesterol levels as it can reduce the bile acid pool<sup>30</sup>. Gayathri et al.<sup>31</sup> checked the effect of LSP on lipid profile and anthropometric changes in a pre - post experimental study on 40 subjects in Chennai, Tamilnadu. Subjects underwent LSP once a week for a total of 8 weeks. Total cholesterol level decreased from 147.675 to 137.325, triglyceride decreased from 124.32 to 108.7, very low - density lipoprotein decreased from 24.865 to 21.74, High - density lipoprotein increased from 30.775 to 33.925 and low - density lipoprotein decreased from 92.035 to 81.66 at p<0.0001. In anthropometric parameter average reduction in weight from 87.82 to 82.7, in Body Mass Index from 34.07 to 32.055, in waist circumferences from 111.825 to 103.625, in hip circumferences from 119.5 to 113.77 and in waist - hip ratio from 0.9344 to 0.9111 was found at p<0.0001. Whereas no statistically significant reduction was noticed in blood pressure and pulse rate. Abdominal obesity is a risk factor for cardiovascular disease and about 60 - 70% of obese people are dyslipidemic<sup>32</sup>. So, LSP can be a safe treatment option for reducing LDL levels and BMI among obese people.

### Effectiveness in preparation of Colonoscopy:

There are several methods used for the preparation of a colonoscopy, as LSP is one of the unique techniques which can be used in the preparation of a colonoscopy. In a study conducted by Arya V et. al<sup>33</sup>, the aim of the study was to compare NuLyteLy (<sup>®</sup>) (PEG - 3350, sodium chloride, potassium chloride, and sodium bicarbonate) and yoga (LWS/yoga) as a colonoscopy in preparation. Information was gathered on the effectiveness of bowel preparation, patient security, patient acceptance, and adverse effects. The results showed that colon preparation with LWS/yoga under supervision was superior to colon preparation using Nulytely as instructed. Shankhprakashalana is an effective tool for colonoscopy preparation. In another study, for preparation of the intestine for a colonoscopy, the effectiveness and safety of SP and PEG (Polyethylene glycol) were done. Before the colonoscopy, the SP method was performed in the morning under the guidance of a yoga instructor. In terms of a procedure for preparing for a colonoscopy with higher tolerability and fewer side effects, the traditional yoga practice known as "Shankha Prakshalana" is preferable to the usual PEG - electrolyte solution<sup>34</sup>.



### 3. Discussion

Bowel health is specially taken care of in *Ayurveda* as it is considered to be associated with many health - related problems such as constipation, IBS, colitis, etc. These studies show no altered health effect on any individual. After LSP sessions, there were no negative side effects; nevertheless, there was a substantial (P 0.001) decrease in blood pressure, pulse rate, and breathing rate<sup>10</sup>. LSP also resulted in greater bowel clearance. Future studies may be designed to look at the long - term benefits of LSP. Studies must be planned to compare LSP with less intensive bowel cleansing techniques like enemas or less potent laxatives as a control intervention.

### 4. Conclusion

All bodily systems are connected with the gastrointestinal tract directly or indirectly. If natural treatments are given like cleansing the tract or stimulating it to function properly, it can be beneficial for the digestive as well as other systems also, as observed in the study. Thus, it is concluded that targeting the bowel for problems like obesity, hypertension, earlier cases of renal failure, constipation, and chronic low back pain is safe and effective. As a result, this yogic exercise can be regularly recommended in cleansing modalities of Naturopathic and yogic treatments. In a healthy person, practicing LSP once a week for four weeks is safe and beneficial. To verify the finding's, large - scale randomized trials are necessary.

Which is not harmful to the body. As the changes are not varying too much thus a person cannot get exerted. The practice only increase the motility of alimentary canal, which may immediately influence the digestion, absorption and assimilation of the body. Which is not harmful to the body. As the changes are not varying too much thus a person cannot get exerted. The practice only increase the motility of alimentary canal, which may immediately influence the digestion, absorption and assimilation of the body.

### References

- [1] Riley D. Hatha yoga and the treatment of illness. *Altern Ther Health Med*.2004 Mar - Apr; 10 (2): 20 - 1. PMID: 15055088.
- [2] Saraswati SM, Saraswati SS. *Hatha Yoga Pradipika*. Yoga Publications Trust; 1998.
- [3] Patra SK. Physiological effect of kriyas: Cleansing techniques. *International journal of Yoga - Philosophy, Psychology and parapsychology*.2017 Jan 1; 5 (1): 3.
- [4] Digambarji S, ML G. *Gheranda Samhita*. Kaivalyadhama SMYM Samiti, Lonavla.1978.
- [5] Gupta R, Gaur K, Ram CV. Emerging trends in hypertension epidemiology in India. *Journal of human hypertension*.2019 Aug; 33 (8): 575 - 87.
- [6] Prenissl J, Manne - Goehler J, Jaacks LM, Prabhakaran D, Awasthi A, Bischops AC, Atun R, Bärnighausen T, Davies JI, Vollmer S, Geldsetzer P. Hypertension screening, awareness, treatment, and control in India: a nationally representative cross - sectional study among individuals aged 15 to 49 years. *PLoS medicine*.2019 May 3; 16 (5): e1002801.
- [7] <https://www.nhs.uk/conditions/high-blood-pressure-hypertension/> (retrieved at 21: 42pm, 27/09/2020)
- [8] Park SH, Han KS. Blood pressure response to meditation and yoga: a systematic review and meta - analysis. *The Journal of Alternative and Complementary Medicine*.2017 Sep 1; 23 (9): 685 - 95.
- [9] Santisteban MM, Qi Y, Zubcevic J, Kim S, Yang T, Shenoy V, Cole - Jeffrey CT, Lobaton GO, Stewart DC, Rubiano A, Simmons CS. Hypertension - linked pathophysiological alterations in the gut. *Circulation research*.2017 Jan 20; 120 (2): 312 - 23.
- [10] Mashyal P, Bhargav H, Raghuram N. Safety and usefulness of Laghushankhaprakshalana in patients with essential hypertension: A self controlled clinical study. *Journal of Ayurveda and integrative medicine*.2014 Oct; 5 (4): 227.
- [11] <https://www.mayoclinic.org/healthy-lifestyle/consumer-health/answers/colon-cleansing/faq-20058435> (retrieved at 18: 53pm, 29/09/2020)
- [12] Kumar K, Kulshrestha A. LaghooŚankhaPrakshālana: Is It an Influential Factor in General Health Status. *Yoga Mimamsa*.2011 Jan.
- [13] Kiran S, Sapkota S, Shetty P, Honnegowda TM. Effect of yogic colon cleansing (laghusankhaprakshalana kriya) on bowel health in normal individuals. *Yoga Mimamsa*.2019 Jan 1; 51 (1): 26.
- [14] Ray G. Evaluation of the symptom of constipation in Indian patients. *Journal of Clinical and Diagnostic Research: JCDR*.2016 Apr; 10 (4): OC01.
- [15] Prakash S, Mangal G, Garg G. VIRECHANA (THERAPEUTIC PURG FOR PITTA VIKARAS).
- [16] Kiran S, Sapkota S, Shetty P, Honnegowda TM. Effect of yogic colon cleansing (laghusankhaprakshalana kriya) on bowel health in normal individuals. *Yoga Mimamsa*.2019 Jan 1; 51 (1): 26.
- [17] Sperber AD, Dumitrascu D, Fukudo S, Gerson C, Ghoshal UC, Gwee KA, Hungin AP, Kang JY, Minhu C, Schmulson M, Bolotin A. The global prevalence of IBS in adults remains elusive due to the heterogeneity of studies: a Rome Foundation working team literature review. *Gut*.2017 Jun 1; 66 (6): 1075 - 82.
- [18] Chong PP, Chin VK, Looi CY, Wong WF, Madhavan P, Yong VC. The microbiome and irritable bowel syndrome—a review on the pathophysiology, current research and future therapy. *Frontiers in microbiology*.2019 Jun 10; 10: 1136.
- [19] Saraswati SN. *Hatha Yoga Book - 3 (Shatkarma)*. Munger: Yoga Publication Trust; 2013
- [20] Singh SN, Jaiswal V, Maurya SP. “SHANKHA PRAKSHALANA” (GASTROINTESTINAL LAVAGE) IN HEALTH AND DISEASE. *Ancient science of life*.1988 Jan; 7 (3 - 4): 157.
- [21] Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systematic review. *Revista de saude publica*.2015 Oct 20; 49: 73.
- [22] Arai YC, Shiro Y, Funak Y, Kasugai K, Omichi Y, Sakurai H, Matsubara T, Inoue M, Shimo K, Saisu H, Ikemoto T. The association between constipation or stool consistency and pain severity in patients with

- chronic pain. *Anesthesiology and pain medicine*.2018 Aug; 8 (4).
- [23] Gupta S, Patil V, Sharma R. Diagnosis and management of Katishoola (low back pain) in Ayurveda: A critical review. *Ayushdhara*.2016; 3: 764 -9.
- [24] Guruprasad K. Understanding Shatkriyas of Yoga through Ayurveda. *International Journal of Ayurveda and alternative Medicine*.2014; 2: 1 - 2.
- [25] Haldavnekar RV, Tekur P, Nagarathna R, Nagendra HR. Effect of yogic colon cleansing (LaghuSankhaprakshalana Kriya) on pain, spinal flexibility, disability and state anxiety in chronic low back pain. *International Journal of Yoga*.2014 Jul; 7 (2): 111.
- [26] Ahirwar R, Mondal PR. Prevalence of obesity in India: A systematic review. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*.2019 Jan 1; 13 (1): 318 - 21.
- [27] Ugwuja EI, Ogbonna NC, Nwibo AN, Onimawo IA. Overweight and obesity, lipid profile and atherogenic indices among civil servants in Abakaliki, South Eastern Nigeria. *Annals of medical and health sciences research*.2013 Apr 23; 3 (1): 13 - 8.
- [28] Hruby A, Hu FB. The epidemiology of obesity: a big picture. *Pharmacoeconomics*.2015 Jul 1; 33 (7): 673 - 89.
- [29] Cramer H, Thoms MS, Anheyer D, Lauche R, Dobos G. Yoga in women with abdominal obesity—a randomized controlled trial. *DeutschesÄrzteblatt International*.2016 Sep; 113 (39): 645
- [30] Tiwari SP, Roy D. A STUDY ON THE EFFECT OF SHATKARMA ON BODY WEIGHT IN THE PATIENTS OF DIABETES MELLITUS.2013; 95 (3): 18–20.
- [31] Gayathri A. Effect of LaghooShankaparakshalana on Lipid Profile and Anthropometric Measurements in Obese Persons (Doctoral dissertation, Government Yoga and Naturopathy Medical College, Chennai).
- [32] Feingold KR. Obesity and dyslipidemia. *Endotext [Internet]*.2020 Nov 2.
- [33] Arya V, Gupta KA, Arya SV. Efficacy of bolus lukewarm saline and yoga postures as colonoscopy preparation: a pilot study. *J Altern Complement Med*.2010 Dec; 16 (12): 1269 - 77. doi: 10.1089/acm.2010.0166. Epub 2010 Nov 29. PMID: 21114406.
- [34] Chouhan MI, Panigrahi MK, Manik R, Nayak HK, Bhat SJ, Sethi S, Makashir MS, Kumar C, RU AG, Haridas MP, Mohan B. S192 Efficacy and Safety of ShankhaPrakshalana, a Yogic Technique versus Polyethylene Glycol Solution for Bowel Preparation in Colonoscopy: A Randomized Controlled Trial. *Official journal of the American College of Gastroenterology| ACG*.2021 Oct 1; 116: S86.