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Original Article

Normal Values of High-resolution Anorectal Manometry of Healthy Indians

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Background/Aims
High-resolution anorectal manometry (HRAM) measures anal sphincter function and anorectal co-ordination. This study aims to provide normal data for HRAM and evaluate the effect of gender, age, and body mass index (BMI) on anorectal functions in healthy Indian subjects.

Methods
HRAM was performed on 93 healthy volunteers using a 20-channel, water-perfused catheter. We evaluated anorectal pressures, rectal sensation, and balloon expulsion time. Measurements were recorded during rest, squeeze, and simulated defecation (push).

Results
Median anal resting pressure (88 mmHg vs 94 mmHg, P = NS), anal squeeze pressure (165 mmHg vs 147 mmHg, P = NS) were not significantly different between males and females. Rectal pressure (70 mmHg vs 54 mmHg, P = 0.024) and anal pressure (82 mmHg vs 63 mmHg, P = 0.008) during simulated evacuation without rectal distention, were higher in males. The threshold for the first sensation was lower in females (40 mL vs 30 mL, P = 0.021) but desire to defecate (105 mL vs 90 mL, P = NS) and maximum tolerable volume (160 mL vs 140 mL, P = NS) were not significantly different in males and females. Anal residual pressure (median mmHg 83 vs 71 mmHg, P = 0.025) was higher in subjects < 40 years of age. Maximum anal squeeze pressure (185 mmHg vs 165 mmHg, P = 0.024) and maximum rectal pressure (75 mmHg vs 62 mmHg, P = 0.032) during push higher in BMI < 23 kg/m^2.

Conclusions
The present study provides normal data for the Indian population that can be used for comparison and further work. Age, gender, and BMI affect anorectal parameters in HRAM and should be considered while reporting.
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Key Words
Anal canal; Body mass index; Defecation; Healthy volunteers; Manometry

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Introduction

Anorectal manometry (ARM) and rectal balloon expulsion test (BET) act as tests to guide the diagnosis and treatment of anorectal dysfunction.[1] This is particularly true in patients with constipation when pre-emptive management with bulking agents and laxatives fails to show improvement.[2,3] ARM test is used for the evaluation of anal sphincter function and anorectal co-ordination.[4] Compared with other physiologic testing, ARM and BET are easily available, cost-effective, and correlate well with treatment outcomes.[5-8] High-resolution anorectal manometry (HRAM) was launched in 2008.[9] High-resolution manometry catheter has more number of closely spaced sensors which enhances spatial resolution and measure changes in pressure circumferentially; and thus, provide detailed colorful topographical plots of intraluminal pressures in relation to location and minimization of movement artifacts.[10] There is a lack of standardization regarding recording methodology. Also, normative data on the influence of age, gender, and BMI on results of ARM are inadequate and variable.[11] Difference in demographics of study participants compounds this problem of interpretation.[11-14] Factors such as higher BMI and the contractility of anorectal muscles known to vary with age and gender, need to be accounted for before interpretation of normal.[13-15] This study aims to provide a normal dataset of parameters of anal sphincter function, anorectal co-ordination, and rectal sensations using water perfused HRM system on healthy Indian subjects. The study also plans to evaluate the effect of age, gender, and BMI on various parameters of anorectal function. The objective is to develop a reliable normal dataset of ARM values from Indian subjects, to be used as a reference to make a diagnosis and plan therapy in patients with anorectal disorders.

Materials and Methods

The Departments of Gastroenterology at 2 tertiary care institutions recruited subjects in the study. The project was started after approval from the institutional review board at both institutions (Project No. EC/OA-100/2016 and ECARP/2019/49). We selected a total of 147 subjects for the study. Based on history and clinical examination, we excluded 54 subjects. Ninety-three healthy subjects were enrolled for this study, of which 29 were female and 64 were male aged 18 years and older. We randomized male and female subjects into 2 comparable groups. But after criteria exclusion, a smaller number of female patients were able to be recruited in the study.

Asymptomatic attendants of patients coming to the Gastroenterology outpatient department between 2016-2020 were recruited after properly explaining the study protocol to them. Before recruitment, informed consent was taken from study participants. Clinical history (including obstetric history in females) and examination (including per-rectal examination) were conducted in the participants. Subjects were screened using a questionnaire of medical and obstetric history.

Exclusion criteria included a history of constipation, diarrhea, fecal incontinence, irritable bowel syndrome, organic anorectal disorders for instance fissures or abscess, abdominal and anorectal surgery, significant cardiac, pulmonary, neuro-psychiatric, liver and kidney disease, a medication that affect gastrointestinal tract motility, inability to augment anal sphincter tone during a digital rectal exam, and history of obstetrics-associated anal sphincter injury and pregnancy.

Equipment

HRAM (Medical Measurement Systems) was undertaken using a water perfused catheter, having 4.4 mm of outer diameter. It has a latex-free balloon at the tip. It contains 20 pressure channels arranged spirally along the catheter which measure circumferential pressure, first channel is located 3 cm from the balloon with 3 mm spacing between each channel. Before starting the procedure, sensors were zeroed to atmospheric pressure. All channels were checked for pressure, and channel block was removed by flushing it with water. A commercially available manometric system (Medical Measurement Systems) was used for data acquisition and processing. The computer screen displayed the pressure activity in the form of color plots, with pressure magnitude indicated by color intensity.[16]

Study Protocol

A digital rectal examination was done prior to catheter insertion using a gloved lubricated finger. Anal tone and anal squeeze pressure were assessed.[17,18]

There were no dietary restrictions for the participants and they could continue with their routine medications.[19] Bowel preparation was given using sodium phosphate enema 1 hour before commencing study. The examination was started by placing a subject in the left lateral position with hips and knees flexed to a 90-degree angle. A catheter was lubricated and then inserted in the rectum. A 3-minute run-in period was allowed for familiarization to give the patient time to relax and the sphincter tone to return to basal levels.[19] The test was carried out with a 60-second recovery interval between each

maneuver. Each maneuver was performed 3 times.

The following measurements were performed;

(1) Anal resting pressure: The subject was instructed to calm and not to move in the left lateral position for 1 minute and anal resting pressure was measured.

(2) Anal squeeze pressure: The subject was told to squeeze the anal canal as strong as possible 3 times with a 60-second rest given between each squeeze. Anal squeeze pressure is an average of 3 maximum squeeze pressures.

(3) Endurance squeeze pressure: This pressure was recorded by asking the subject to squeeze the anal canal as tight and long as possible.

(4) Push (simulated evacuation) pressure: This was measured first without and then with rectal balloon distension with 50 mL of air. The subject was instructed to push down for 10 seconds as if to defecate and pressure was recorded. Maneuver was done 3 times with a 30-second interval between each push.

(5) The rectoanal inhibitory reflex: Presence or absence of anal sphincter relaxation is noted while injecting up to 50 mL of air into the rectal balloon. A positive rectoanal inhibitory reflex (RAIR) response occurred if there is a 20% greater drop and then returns to the resting pressure.

(6) Rectal sensation: Rectal balloon was inflated with a syringe in 10 mL increments of air and the threshold volume for the first sensation was recorded. After that, the balloon volume was increased by 30 mL, and urge to defecate, and maximum tolerable volume was recorded.

(7) Rectal BET: This was measured as the time required to expel a rectal balloon filled with 50 mL of water in the left lateral position. We do not have a pulley to attach weight and commode facility in our institute for performing the test. Our method of balloon expulsion was based on protocol used in previous studies.[20-22] If more than 1 minute was required to expel the balloon it was considered as failure. In healthy subjects anorectal pressures and rectal compliance are highly reproducible, although sensory thresholds are reproducible to a variable degree, it depends on stimulation and perception intensity.[23]

Statistical Methods

Qualitative data was represented in form of frequency and percentage and compared using the chi-square or Fisher's exact test. Quantitative data was represented using mean, median and interquartile range. Comparison of quantitative data measured between binomial qualitative variables (eg, Age, less than 40 years and more than or equal to 40 years) was done using Unpaired *t* test or by Mann–Whitney *U* test. Reference value calculation for various quantitative variables for various sub-groups based on sex, age-category, and BMI category, was done using "Reference Value Advisor," a freeware set of macroinstructions for Microsoft Excel by Geffre Anne, Concordet Didier, Braun Jean-Pieere, and Trumel Catherine, that compute reference intervals using the standard and robust methods with and without generalized Box-Cox data transformation (http://www.biostat.envt.fr/reference-value-advisor/). An alpha value (*P*-value) of ≤ 0.05 was used as the cutoff for statistical significance. Alpha value of ≤ 0.05 means that there is a less than 5% chance that the data being tested could have occurred under the null hypothesis. Statistics were done using Microsoft Excel (Microsoft Corp, Redmond, WA, USA) and SPSS version 23.0 (IBM Corp, Armonk, NY, USA).

Results

In India the majority of the population is young. In our study population also, the median age was 40 years, so we used 40 years as a cutoff value for comparison.

Demographic parameters of participants are provided in Table 1. Only 30% of subjects (28) were having a sedentary lifestyle like driver, clerk, and shopkeeper, spending more than 50% of their waking hours doing sedentary activities. Out of 29 females, 20 had a normal vaginal delivery without episiotomy. Comparison of Anorectal HRAM parameters in female cohort presented in Supplementary Table 1. Abdominal and anorectal digital examinations were normal in all subjects. All subjects tolerated the procedure without any complications. Measured values for each

Table 1. Demographic Parameters in Study Subjects

Gender		Age		BMI (kg/m^2)		Childbirth		Sedentary lifestyle	
Male	64	Min	18	Underweight (< 18.5)	12.5%	Yes	20	Yes	30%
Female	29	Max	74	Normal (18.5-22.9)	54.7%	No	9	No	70%
		Median		Overweight and obese (> 23)	7.8%				

BMI, body mass index.

Table 2. Measured High-resolution Anorectal Manometry Parameters in Study Subjects

Variable	Male (n = 64)	Female (n = 29)	*P*-value
Anal canal length (cm)	2.5 (1.1-3.8)	1.5 (1-3.2)	0.005
Anal resting pressure (mmHg)	88 (33-132)	94 (48-117)	0.702
Maximum anal squeeze pressure (mmHg)	165 (90-377)	147 (83-259)	0.222
Anal squeeze increment	90 (32-150)	66 (10-160)	0.006
Endurance squeeze pressure (mmHg)	136 (45-199)	127 (86-237)	0.707
Duration of squeeze (seconds)	38 (17-84)	39 (12-68)	0.711
Simulated evacuation without rectal distention			
Maximum rectal pressure	70 (34-133)	54 (26-117)	0.028
Anal residual pressure	82 (36-170)	63 (18-100)	0.008
Rectoanal pressure gradient	−6 (−78-66)	6 (−39-51)	0.001
Anal relaxation %	16 (−38-53)	42 (−24-80)	0.004
Defecation index[a]	0.91 (0.38-2.06)	1.11 (0.45-2.77)	0.077
Simulated evacuation with rectal distention			
Maximum rectal pressure	70 (40-258)	62 (15-129)	0.049
Anal residual pressure	66 (9-163)	51 (8-99)	0.004
Rectoanal pressure gradient	5 (−79-203)	11 (−41-64)	0.002
Anal relaxation %	24 (−58-83)	46 (10-92)	0.004
Defecation index[a]	1.07 (0.4-5.3)	1.22 (0.56-2.80)	0.370
RAIR%	49.5 (0.0-87.0)	44 (17-80)	0.637
Rectal sensation			
First sensation	40 (10-170)	30 (10-80)	0.021
Desire to defecate	105 (40-250)	90 (50-170)	0.092
Maximum tolerable volume	160 (80-310)	140 (80-270)	0.373
Balloon expulsion time (seconds)	60 (14-900)	49 (22-65)	0.186

[a]Intrarectal pressure to anal sphincter residual pressure ratio.
RAIR, rectoanal inhibitory reflex.
Data are presented as median (interquartile range).

variable are presented for all participants in Table 2.

Effect of Gender on Parameters of High-resolution Anorectal Manometry

The difference in the ARM parameters between males and females is mentioned in Table 2. The anal canal length was significantly lower in females compared to males (1.5 cm vs 2.5 cm). The anal squeeze increment was higher in males compared to females ($P < 0.05$). Maximum rectal pressure (median 70 mmHg vs 54 mmHg), anal residual pressure (median 82 mmHg vs 63 mmHg), without rectal balloon inflation, were higher, while anal relaxation rate (median 16% vs 42%) and rectoanal pressure gradient without balloon inflation were lower in males compared to females (median −6 mmHg vs 6 mmHg). Similarly, maximum rectal pressure (median 70 mmHg vs 62 mmHg), anal residual pressure (median 66 mmHg vs 51 mmHg), with rectal balloon inflation were higher while anal relaxation rate (median 24% vs 46%) and rectoanal pressure gradient with balloon inflation were lower in males compared to females (median 5 mmHg vs 11 mmHg). In a rectal sensory test, rectal volume for the first sensation was lower in females (median 30 mL vs 40 mL), while a desire to defecate and maximum tolerable volume showed no difference. Anal resting pressure, anal squeeze pressure, endurance squeeze pressure, duration of endurance squeeze, defecation index, and balloon expulsion time are not affected by gender.

Effect of Age on Parameters of High-resolution Anorectal Manometry

The difference in the ARM parameters according to age is mentioned in Supplementary Table 2. Anal residual pressure (median 83 mmHg vs 71 mmHg) was higher, while rectoanal pressure gradient (median −11.5 mmHg vs 0.0 mmHg), and defecation index (median 0.85 vs 1.00) were lower in subjects < 40 years of age. RAIR (median 53% vs 40%) was high in subjects < 40 years of age. There was no difference in anal canal length, resting and squeeze anal pressure, simulated evacuation with rectal balloon in-

Table 3. Comparison of Results of Previous Studies Examining Anorectal Function in Healthy Cohort

Variable	Gender	Rao et al,[13] 1999	Kritasampan et al,[27] 2004	Gruppo et al,[29] 2010	Gundling et al,[26] 2010	Otto et al,[25] 2013	Carrington et al,[24] 2014	Lee et al,[28] 2014	Present study
N		45	30	52	146	30	115	54	93
Manometry type		Conventional	Conventional	Conventional	Conventional	Conventional	High resolution	High resolution	High resolution
System type		Water perfused	Water perfused	Water perfused	Water perfused	Water perfused	Solid state	Solid state	Water perfused
Age	M	40 (22-68)	32.9 ± 13.2	48 ± 13	64 (22-90)	25 (21-30)	32 (21-72)	37.5 (20.0-67.0)	39 (18-74)
	F	44 (24-71)	31.2 ± 6.6	49 ± 14	64 (23-88)		45 (18-68)		37 (15-64)
Anal canal length(cm)	M	4.0 (3.8-4.2)	3.2 ± 0.7	3.6 (3.0-4.0)			3.8 (2.4-5.3)		2.5 (1.1-3.8)
	F	3.6 (3.4-3.8)	2.5 ± 0.7	3.5 (3.3-4.0)			3.4 (1.6-6.0)		1.5 (1-3.2)
Anal resting pressure (mmHg)	M	72 (64-80)	57.4 ± 16.7	84 (72-93)	67 (30-142)	72.3 ± 13.7	67 (38-136)	46 (39-56)	88 (33-132)
	F	65 (56-74)	52.8 ± 13.4	74 (60-85)	64 (17-126)	69.8 ± 14.5	63 (25-111)	32 (24-42)	94 (48-117)
Maximum anal squeeze pressure (mmHg)	M	193 (175-211)	216.1 ± 75.3	225 (207-279)	201 (69-413)	293.5 ± 97.3	268 (94-732)	178 (140-212)	165 (90-377)
	F	143 (124-162)	110.5 ± 41.3	174 (138-196)	151 (64-418)	180.8 ± 43.5	221 (76-503)	75 (61-89)	147 (83-259)
Duration of squeeze (sec)	M	32 (26-38)		26 (24-27)			19 (3-30)		38 (17-84)
	F	24 (20-28)		26 (24-28)			6 (2-30)		39 (12-68)
Simulated evacuation without rectal distention									
Maximum rectal pressure	M	68 (58-78)					77 (20-140)	69 (44-98)	70 (34-133)
	F	63 (54-72)					57 (18-200)	37 (27-51)	54 (26-117)
Anal residual pressure	M	49 (35-63)					57 (20-104)	26 (13-55)	82 (36-170)
	F	40 (32-48)					43 (12-110)	19 (10-35)	63 (18-100)
Rectoanal pressure gradient	M							30 (5-66)	−6 (−78-66)
	F							16 (5-30)	6 (−39-51)
Anal relaxation %	M	43 (30-56)					21 (0-60)	16 (0-82)	16 (−38-53)
	F	34 (25-43)					23 (0-83)	30 (0-75)	42 (−24-80)
Simulated evacuation with rectal distention									
Maximum rectal pressure	M							53 (31-77)	70 (40-258)
	F							33 (25-41)	62 (15-129)
Anal residual pressure	M							30 (12-48)	66 (9-163)
	F							16 (11-28)	51 (8-99)
Rectoanal pressure gradient	M							29 (1-46)	5 (−79-203)
	F							11 (6-20)	11 (−41-64)
Anal relaxation %	M								24 (−58-−83)
	F								46 (10-92)
Rectal sensation									
First sensation	M	20 (15-25)	14.7 ± 5.1	30 (20-50)	40 (10-100)	42.4 ± 26.1		10 (10-20)	40 (10-170)
	F	19 (15-23)	13.1 ± 4.8	30 (21-40)	35 (10-100)	32.6 ± 11.7		10 (10-20)	30 (10-80)
Desire to defecate	M	109 (85-134)	31.8 ± 12.4	80 (60-100)	120 (50-200)	105.2 ± 33.9		80 (60-120)	105 (40-250)
	F	103 (83-123)	32.3 ± 13	70 (60-80)	90 (45-200)	101.4 ± 22.3		60 (50-70)	90 (50-170)
Maximum tolerable volume	M	249 (223-275)	164.1 ± 44.2	170 (120-180)		195.0 ± 48.3		130 (110-178)	160 (80-310)
	F	230 (205-255)	108.5 ± 44.1	150 (117-155)		163.9 ± 37		115 (98-153)	140 (80-270)
Balloon expulsion time (sec)	M							15 (5-50)	60 (14-90)
	F							15 (10-30)	49 (22-65)

M, male; F, female.
Data are presented as median (interquartile range) or mean (SD).

flation, rectal sensation, and BET with increasing age.

Effect of Body Mass Index on Parameters of High-resolution Anorectal Manometry

The difference in the ARM parameters according to BMI is mentioned in Supplementary Table 3. Maximum anal squeeze pressure (185 mmHg vs 165 mmHg) and squeeze increment pressure (90 mmHg vs 74 mmHg) decrease with BMI. On simulated evacuation without rectal balloon inflation, only maximum rectal pressure was significantly higher in BMI < 23 kg/m^2 (median 75 mmHg vs 62 mmHg). On simulated evacuation with rectal balloon inflation, anal relaxation percentage decrease (median 75% vs 54%) and rectoanal gradient increase (median −13 mmHg vs 7 mmHg) with an increase in BMI. Balloon expulsion time was shorter in BMI > 23 kg/m^2 group (median 47 seconds vs 60 seconds). Anal canal length, anal resting pressure, endurance squeeze, and its duration, defecation index, RAIR %, and rectal sensory volumes do not differ with change in BMI.

We compared the defecation index according to gender, age, and BMI, but only subjects with age > 40 years had a significantly higher defecation index (without rectal balloon distension) compared to < 40 years. In all other groups, the difference was nonsignificant. Values of the defecation index are mentioned in a table provided in the supplement.

Discussion

A comparison of previous studies on normal data in ARM is shown in Table 3. As compared to previous studies, anal resting pressure in the present study was high in both genders.[13,24-28] Other previous studies had higher anal squeeze pressure in males as compared to the present study. Anal squeeze pressure in females was comparable to most of the previous data.[13,25,26,28,29] Maximum rectal pressure during simulated evacuation (without balloon inflation) was comparable, whereas anal residual pressure (without balloon inflation) was higher concerning previous studies.[13,24,28]

Prolonged BET and negative anorectal gradient are widely used to diagnose dyssynergic defecation disorders.[30,31] In the present study, anorectal pressure gradient was negative during simulated evacuation in 56 (60%) and 39 (41%) subjects without and with balloon inflation respectively, whereas thirty-one (33%) subjects failed to expel balloon in 1 minute. In 1 study anorectal pressure gradient was positive in all study participants but balloon expulsion failed in 14.8% (8 of 54) subjects.[28] But, in a study on asymptomatic healthy females by Noelting,[14] a anorectal gradient was negative in all females (30 of 62) aged < 50 years, and out of that only 5 had abnormal balloon expulsion test.

This suggests that a negative anorectal gradient by HRM does not necessarily indicate dyssynergia, also prolonged BET is not associated with anorectal gradient.[13,14,24,28,32,33] There is considerable overlap in anorectal gradient value between asymptomatic and dyssynergic populations. Patients with pelvic pain can have reduced anorectal gradients.[3] These findings suggest that anorectal gradient during a simulated evacuation is not a reliable parameter to diagnose defecatory disorders. The reason for this difference may be due to the difference between actual and simulated defecation.[32,33] While the first sensation and desire to defecate was comparable to most of the previous studies, 1 study had a much lower sensation for a desire to defecate (31.8 mmHg and 32.3 mmHg) compared to our study (105 mmHg and 90 mmHg) in males and females, respectively. In a study by Rao et al,[13] maximum tolerable volume was higher (249 mmHg and 230 mmHg) compared to the present study (160 mmHg and 140 mmHg) in males and females, respectively.[24-28]

There was no significant effect of gender on anal resting pressure in the present study. Our results were consistent with previous studies.[4,13,24-27,29,34-36] Anal resting pressure was low in females compared to males in a study done by Lee et al[28] and Coss-Adame et al.[37]

Maximum anal squeeze pressure were higher in males but it was not statistically significant consistent with results obtained in a study by Carrington et al.[24] As testosterone causes muscle growth, males have more muscle mass and strength as compared to females which are probably responsible for this difference.[38] The threshold for rectal sensation was lower in females with statistical significance in first sensation consistent with a previous study.[26,28] Difference in sensory nerve function in females may explain this difference.[28] BET did not show a significant difference concerning gender.

In the present study, most of the parameters did not differ according to age.[13,24,27,28] Few studies are consistent with our results,[14] but some found statistically significant low anal resting and squeeze pressure in older subjects.[1,4,26,35-37] The reason for a lower anal resting pressure in older age may be because of the internal sphincter muscle fibrosis in elder people.[39] With age, skeletal muscle mass decrease, that may be a reason for lower anal squeeze pressure.[38] Anorectal pressure gradient increases and anal residual pressure decrease with age when measured without balloon inflation during simulated evacuation.[4,14] Rectal sensation did not change with age consistent with a previous study.[14,27] BET was similar in both groups consistent with 2 previous studies[1,27] but 2 other studies

found shorter BET in older subjects.[4,14] Studies evaluating the influence of BMI on anorectal parameters in normal subjects are sparse.[1,4,28] Anal resting pressure did not show any change with BMI, but anal squeeze pressure decreases with an increase in BMI. A previous study reported higher squeeze pressures in overweight and obese women with fecal incontinence compared with women of normal weight.[40] High BMI positively correlated with anorectal gradient and negatively correlated with BET but showed no relation with rectal sensations. The above findings showed higher BMI may be responsible for fecal incontinence.[41] In a study by Lee et al[28] BMI positively correlated with anal resting pressure and anorectal gradient during simulated evacuation without rectal balloon inflation. Difference in a demographic, instrument, and variable methodology used may have caused an observed difference in measured parameters.

This is the first prospective study to define normative data on ARM from India. Some limitations of the study include the small number of female participants. Tests to determine the integrity of anal sphincter in healthy participants such as endoanal ultrasound was not undertaken so asymptomatic structural abnormalities cannot be ruled out. The method of balloon expulsion is not standardized as we have not used pulleys or the sitting position. Some obstetric variables (mode of delivery, obstetric trauma, and number of deliveries) may have affected anorectal parameters in women with vaginal delivery but which were not evaluated.

Conclusion

The present study provides normal data for the Indian population that can be used for comparison and further work. Age, gender, and BMI affect most of the anorectal parameters in HRAM and should be taken into consideration while reporting results.

Supplementary Materials

Note: To access the supplementary tables mentioned in this article, visit the online version of *Journal of Neurogastroenterology and Motility* at http://www.jnmjournal.org/, and at https://doi.org/10.5056/jnm21107.

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