



CHRONIC RHINOSINUSITIS: TREATMENT!! ANULOMA VILOMA EXERCISE AND HYPERTONIC SALINE NASAL IRRIGATION AS AN ADJUNCT TO MAXIMAL MEDICAL THERAPY

Otolaryngology

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ABSTRACT

The objective of this study is to evaluate effectiveness of hypertonic nasal saline irrigation and Anuloma viloma exercise for improving severity, frequency of sinus symptoms and quality of life in chronic rhinosinusitis with patients taking only maximal medical therapy. In this prospective clinical study, 56 patients with chronic rhinosinusitis were enrolled and divided into 3 groups according to treatment given with group 1 (MMT-maximal medical therapy), group 2 (MMT with hypertonic nasal saline irrigation) and group 3 (MMT with Anuloma viloma exercise). Patients were evaluated before treatment and at 3 and 6 months after treatment as per symptoms score (VAS, SNOT-20, GQ, RSDI) and sign scoring (CT scan and nasal endoscopy). Maximum improvement in symptom score was 54.43%, 72.42% and 67.69% in group 1, 2 and 3 respectively that occurred after 3 months, then improvement were 76.49%, 86.25% and 84.5% in group 1, 2 and 3 respectively at 6 months. Maximum improvement in sign score was 49.93%, 63.16% and 53.81% in group 1, 2 and 3 respectively that occurred after 3 months, then improvement were 81.11%, 90.95% and 84.61% in group 1, 2 and 3 respectively at 6 months. MMT with Anuloma viloma exercises improves quality of life in CRS. Our study recommends a combination of both MMT and hypertonic saline irrigation with anuloma viloma exercises at improving the symptom severity, symptom frequency, sign scores and quality of life in patients of CRS.

KEYWORDS

chronic rhinosinusitis, maximal medical therapy, hypertonic nasal saline irrigation, anuloma viloma exercise.

INTRODUCTION

Chronic rhinosinusitis (CRS) is a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses for at least 12 weeks duration. (Michael S. Benninger, 2003)¹. This is an inflammatory response involving the mucous membrane of the nasal cavity and para-nasal sinuses, fluid within these cavities and/or the underlying bone. The prevalence of sinusitis is estimated to be 14% of the global population, more in places with high levels of atmospheric pollution, damp temperate climates, along with higher concentrations of pollens². Patients with allergy, asthma, history of transplants and immunocompromised state e. g. AIDS develop sinusitis more often³. The principles involved in the management of chronic rhinosinusitis are to identify, treat the underlying cause and also, if possible, to restore the functional integrity of the inflamed mucosal lining. Restoration of sinus ventilation and correction of mucosal opposition will allow restoration of the mucociliary system. The goals of medical therapy for CRS are to reduce mucosal edema, promote sinus drainage, and eradicate infections that may be present. This often requires a combination of topical or oral glucocorticoids, antibiotics and nasal irrigation. Other agents include decongestants, antihistamines, mast cell stabilizer and expectorants. Hypertonic nasal saline irrigation is a therapy that flushes the nasal cavity with saline solution, facilitating a wash of the structures within. Hypertonic saline improves mucociliary clearance, thins mucus, and may decrease inflammation. If these measures fail, the patient is considered for endoscopic drainage of ostiomeatal complex, which helps to restore mucociliary clearance and normal airflow. Surgical care is usually reserved for cases that are refractory to medical treatment and for patients with anatomic obstruction. Yogas like Anuloma Viloma Exercise includes "Alternate nostril breathing technique" helps in prevention of rhinosinusitis.

Our aim of the present study is to see the effectiveness of Saline Nasal Irrigation and Anuloma Viloma exercises for improving the severity, frequency of sinus symptom and quality of life in Chronic rhinosinusitis with patients taking only Maximal Medical Therapy.

PATIENTS AND METHODS

The study was a prospective, randomized, single blind type of study of

one year conducted in the Department of ENT and Head & Neck Surgery, in 56 patients with chronic rhinosinusitis after due clearance from the Institutional Ethics Committee.

Inclusion criteria

Patients included were patients with at least 2 major factors or 1 major and 2 minor factors must be present for at least 12 weeks' duration (major factors like facial pain/pressure, nasal obstruction, nasal discharge/discholorated postnasal drip, hyposmia/anosmia, purulence on examination, and fever; minor factors like headache, non-acute fever, halitosis, dental pain, fatigue, cough, and ear pain/pressure/fullness). Patients with edema / discharge within the middle meatus or ethmoid region on endoscopy and evidence of CRS on CT scans within one year of study were included in the study.

Exclusion criteria

Patients not willing to give consent, allergic to medications of MMT, CRS with sinonasal polyp or allergic fungal rhinosinusitis, complicated sinusitis (e.g. sinonasal malignancy, osteomyelitis, abscess, etc.), pregnant and lactating females were not included in the study

Procedure

All the patients were selected as per diagnostic criteria given by *Rhinosinusitis Task Force* (RTF) in 2003⁴ i.e. symptoms persisting for more than 12 weeks, persisting inflammatory changes on imaging and nasal endoscopy. The study consisted of 3 groups where group 1 consists of 18 cases treated by Maximal Medical Therapy (MMT), group 2 consisting of 20 cases by MMT and 3.5% hypertonic saline douching as adjuvant, two times a day in both nostrils, and group 3 consisting of 18 cases by MMT and Anuloma Viloma exercises. The patients in the group were selected randomly i.e. in a lottery basis and the observers were not aware of the treatment given to the patient by the doctor. A detail history was taken by the patients including their symptoms and complete otorhinolaryngological examination with nasal endoscopy and CT scan of nose and paranasal sinuses were performed before and after the medical treatment.

Visual Analogue score (VAS) (Hayes and Patterson, 1921)⁵ of 0 to 10

was used to evaluate symptoms (where 0=no symptom and 10= most severe symptom) for nasal congestion, headache, facial pain, nasal discharge, olfactory disturbances and overall symptomatic discomfort. Sinonasal outcome test (SNOT-20) (Piccirillo JF, Merritt Jr. MG, Richard ML, 2002)⁶ questions and each question graded 0 to 5 according to severity of symptoms was used. (0=no problem, 1=very mild problem, 2=mild or slight problem, 3=moderate problem, 4= severe problem, 5=problem 'as bad as it can be'). The total SNOT-20 score is calculated as the mean item score for all 20 items.

Global question (GQ) measures symptom frequency over last 2 weeks and was graded from 1 to 5 (1=never, 2=rarely, 3=seldom, 4=often, 5=always).

Rhin sinusitis Disability Index (RSDI) (Benninger MA, Senior BA, 1997)⁷ assessed patients' quality of life. RSDI consist of 30 questions and each question graded from 0 to 4 according to severity of disability (0=never, 1= almost never, 2=sometimes, 3=almost always, 4=always).

The CT scan finding was assessed using a scoring system (Kennedy, 1992)⁸ for each of the sinuses (maxillary, anterior ethmoid, posterior ethmoid, frontal and sphenoid sinuses) for 0 to 2 (where 0=no abnormality, 1=partial opacification, 2=total opacification) and 0 or 2 for the osteomeatal complex (0=non-occluded and 2=occluded). A maximum score of 24 was thus possible and each side should be considered separately.

The Endoscopic appearances (Lund and Mackay, 1993)⁹ were quantified on 0 to 2 point basis in the presence of polyp, discharge and edema.

- Polyp:0=absence, 1=in meatus, 2=beyond meatus
- Edema; 0=absence, 1=mild, 2=severe
- Discharge; 0=absence, 1=clear or thin, 2=thick or purulent

VAS, SNOT-20, GQ, RSDI, Endoscopy and CT scan was done before treatment (baseline) and at an interval of 3month and 6months after starting of treatment.

MMT included Macrolides (Tb. Clarithromycin 250mg 1BD 7 days, then 250mg OD x3months), systemic steroid (prednisolone),topical nasal corticosteroid (mometasone furoate 2puff OD), systemic decongestants and mucolytics for 3 months.

Table 1: Pretreatment and Post-treatment symptom scoring

		Group 1				Group 2				Group 3			
		Average VAS	Average SNOT-20	Average GLOBAL QUESTION	Average RSDI	Average VAS	Average SNO T-20	Average GLOBAL QUESTION	Average RSDI	Average VAS	Average SNO T-20	Average GLOBAL QUESTION	Average RSDI
Pre treatment score	39.66	2.87	4.4	32.2	39.60	2.85	4.6	33.45	39.88	2.82	4.5	34.28	
Improvement at 3 months	Score	12.11	1.21	2.95	13.7	9.35	0.58	2.2	6.2	11.72	1.05	2.27	4.17
	Pretreatment score – Score (3months) X 100 Pretreatment score (in percentage)	69.46 %	57.84 %	33.0%	57.45%	76.4%	79.64%	52.17%	81.46%	70.61%	62.76%	49.55%	87.83%
	Average of scores (VAS,SNOT-20,GQ,RSDI)	54.3 %	72.42 %	67.69%									
Improvement at 6 months	Score	5.6	0.57	1.88	5.89	3.55	0.27	1.15	3.9	5.3	0.53	1.16	1.39
	Pretreatment score – Score (6 months) X 100 Pretreatment score (in percentage)	85.87 %	80.1%	57.27%	81.70%	91%	90.52%	75%	88.34%	86.71%	81.20%	74.22%	95.94%
	Average of scores (VAS,SNOT-20,GQ,RSDI)	76.49 %	86.25 %	84.5%									

3.5% hypertonic saline nasal douching done by a 50 ml syringe bulb for irrigating the nasal cavity involving pouring of the saline solution into one nostril while the other held closed, so that the solution runs out of the mouth and the same was repeated for the other nostril. This technique was practiced twice daily for 3 months.

Anuloma viloma exercises included “Alternate nostril breathing technique”. It is as follows: close the right nostril with the right hand thumb,inhale slowly through the left nostril, till the lungs are completely filled and then close the left nostril with the second and third fingers and open the right nostril to exhale but slowly, exhale till the lungs are completely empty. The process of 'inhale with left nostril and exhale with right' is “one cycle” then 'inhale with the right nostril and exhale with left' is the “second cycle” and so on. This technique was practiced for 3 minutes daily, at least in the beginning or as per body strengths for 3 months.

MMT, MMT with nasal saline irrigation and MMT with Anuloma viloma exercises were given to respective allotted patients initially for 12 weeks and then patients were evaluated as per symptom scores, i.e. VAS, SNOT-20, GQ, RSDI and sign scores i.e. nasal endoscopy and CT scan.

For statistical analysis student't' test and one way ANOVA test was used. Student't' test was used to compare the statistical significance of various symptom and sign score of two groups at a time of 3 and 6months.One way ANOVA test was used to compare all the three groups at a time and for confirming the statistical significance of student 't' test. p value < 0.05 is considered statistically significant.

RESULTS

The study comprised of 56 patients with age range 15-58 years and most of the patients suffering from CRS were in the third decade (19,33.92%) followed by the fourth decade (14,25%) ; with 16% in second decade and 12.5% in fifth and sixth decade each. In the present study most of the patients were in age group 21-30 years comprising about 32.05% in group 1, 42.1% in group 2 and 36.8% in group 3.

There was a male preponderance with 66.08% male (n=37) and 33.92% females (n=19).In the study , group 1 comprised of 11 males and 7 females (M:F ratio = 1:0.64) , group 2 comprised of 14 males and 6 females (M:F ratio = 1:0.43) and group 3 comprised of 12 males and 6 females (M:F ratio = 1:0.5).

Table 1 shows maximum improvement in symptom score was (54.43%, 72.42% and 67.69% in group1 (MMT), 2 (MMT with saline irrigation) and 3 (MMT with anuloma viloma exercises) respectively

that occurred after 3months, then improvement were (76.49%, 86.25% and 84.5% in group 1 (MMT), 2 (MMT with saline irrigation) and 3 (MMT with anuloma viloma exercises) respectively at 6months.

Table 2: Pretreatment and Post-treatment Sign scoring

	Group 1		Group 2		Group 3	
	Endo-scopic score	CT score	Endo-scopic score	CT score	Endo-scopic score	CT score
Pre-treatment	4.67	11.08	4.80	11.53	4.78	11.46
improve-ment at 3 months after treatment	Score					
	2.78	4.5	2.10	3.45	2.33	5.0
	Pretreatment score – Score (3months) X 100 Pretreatment score (in percentage)					
	40.47%	59.38%	56.25%	70.07%	51.25%	56.36%
	Average of Endoscopic and CT score					
	49.93%	63.16%	53.81%			
improve-ment at 6 months after treatment	Score					
	0.89	2.08	0.5	0.88	0.72	1.8
	Pretreatment score – Score (6 months) X 100 Pretreatment score (in percentage)					
	80.94%	81.28%	89.53%	92.36%	84.93%	84.29%
	Average of Endoscopic and CT score					
	81.11%	90.95%	84.61%			

Table 2 shows maximum improvement in sign score was (49.93%, 63.16 % and 53.81 % in group 1 (MMT), 2 (MMT with saline irrigation) and 3 (MMT with anuloma viloma exercises) respectively that occurred after 3months, then improvement were (81.11%, 90.95 % and 84.61% in group 1 (MMT), 2 (MMT with saline irrigation) and 3 (MMT with anuloma viloma exercises) respectively at 6months.

GQ	5.15	0.0001	6.50	0.0001	6.11	0.0001
RSDI	9.67	0.0001	5.82	0.0001	8.45	0.0001
Endoscopic score	4.62	0.0001	5.28	0.0001	5.59	0.0001
CT score	7.61	0.0001	8.32	0.0001	10.42	0.0001

Table 3 shows symptom severity according to VAS and SNOT-20 was better improved in all the groups at 6 months than at 3 months and it was statistically significant (p<0.05),symptom frequency (by global question) and quality of life (by RSDI) was better improved in all the groups at 6 months than at 3 months and it was statistically significant (p<0.05) and Endoscopic score and CT score were better improved in all the groups at 6 months than at 3 months and it was statistically significant (p<0.05).

Table 3 : Analysis of various scores in all the 3 groups at 3

Comparison	3 months vs 6 months					
	Group 1		Group 2		Group 3	
	t value	p value	t value	p value	t value	p value
VAS	10.77	0.0001	13.36	0.0001	12.40	0.0001
SNOT-20	14.59	0.0001	10.52	0.0001	7.78	0.0001

Table 4 : Comparison in average mean of various scores in all the 3 groups at 3 months and 6 months

	Group 1		Group 2		Group 3	
	3 month	6 month	3 month	6 month	3 month	6 month
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD
VAS	13.11± 2.68	5.61± 1.26	9.35± 1.6	3.55± 1.1	11.72± 1.96	5.39± 0.92
SNOT-20	1.21±0.15	0.57± 0.11	0.59± 0.11	0.27± 0.08	1.05± 0.24	0.54± 0.14
Global Question	2.94± 0.64	1.89± 0.58	2.2± 0.62	1.15± 0.37	2.28± 0.67	1.17± 0.38
RSDI	13.67± 3.18	5.89± 1.68	6.2± 1.44	3.9± 1.02	4.16± 1.1	1.39± 0.85
Endoscopic score	2.78± 1.56	0.89± 0.76	2.1± 1.21	0.5± 0.61	2.33± 1.08	0.72± 0.57
CT score	4.5± 1.17	2.08± 0.67	3.47± 1.19	0.88± 0.72	5.0± 1.08	1.85± 0.69

Table 4 shows symptom severity according to VAS and SNOT-20, & symptom frequency according to GQ is best improved in Group 2 (MMT with saline nasal irrigation) than in group 1 (MMT) and 3 (MMT with anuloma viloma exercises) at both 3 month and 6 months.. Quality of life according to RSDI is best improved in Group 3 than in group 1 and 2 at both 3 month and 6 months.Sign score according to Endoscopy and CT is best improved in Group 2 than in group 1 and group 3 at both 3 and 6 months.

CT Score	Group 1 vs Group 2		Group 1 vs Group 3		Group 2 vs Group 3	
	t value	p value	t value	p value	t value	p value
		2.68	0.0109	5.3	0.0001	1.33
	4.1332	0.0002	4.2	0.0002		

Table 5 Analysis of statistical significance of groups with various scores

VAS SNOT-20	Comparison	3 month		6 month	
		t value	p value	t value	p value
	Group 1 vs Group 2	5.31	0.0001	5.42	0.0001
Group 1 vs Group 3	1.77	0.0847	0.60	0.5405	
Group 2 vs Group 3	4.10	0.0002	5.55	0.0001	
Group 1 vs Group 2	14.63	0.0001	9.68	0.0001	
Group 1 vs Group 3	2.39	0.0221	0.71	0.4796	
Group 2 vs Group 3	7.72	0.0001	7.39	0.0001	
GLOBAL QUESTION	Group 1 vs Group 2	3.61	0.0009	4.73	0.0001
	Group 1 vs Group 3	3.0221	0.0047	4.4	0.0001
	Group 2 vs Group 3	0.38	0.70	0.16	0.87
RSDI	Group 1 vs Group 2	9.49	0.0001	4.46	0.0001
	Group 1 vs Group 3	11.97	0.0001	10.94	0.0001
	Group 2 vs Group 3	4.84	0.0001	8.18	0.0001
ENDOSCOPIC Score	Group 1 vs Group 2	1.5	0.1398	1.75	0.0882
	Group 1 vs Group 3	1.00	0.32	0.75	0.45
	Group 2 vs Group 3	0.61	0.54	1.14	0.2598

Table 5 shows :

- Group 2 is better than Group 1 and 3 at improving symptom severity (VAS and SNOT-20) and it is statistically significant (p<0.05) at both 3 month and 6 months.
- Group 3 is better than Group 1 at improving symptom severity (VAS and SNOT-20) but it is statistically NOT significant (p>0.05) at both 3 month and 6 months.
- Group 2 and 3 is better than Group 1 at improving symptom frequency (GQ) and it is statistically significant (p<0.05) at both 3 month and 6 months.
- Group 2 is better than Group 3 at improving the symptom frequency (GQ), but it is statistically NOT significant (p>0.05) at both 3 month and 6 months.
- Group 2 and 3 is better than Group 1, & group 3 is better than group 2 at improving quality of life (RSDI) and it is statistically significant (p<0.05) at both 3 month and 6 months
- Group 2 and 3 is better than Group 1, & group 2 is better than group 3 at improving Endoscopic score, but it is statistically NOT significant (p>0.05) at both 3 month and 6 months.
- Group 2 is better than Group 1 and 3 at improving CT sign score and it is statistically significant (p<0.05) at both 3 month and 6 months.
- Group 1 is better than Group 3 at improving CT sign score, but it is statistically NOT significant (p>0.05) at both 3 month and 6 months.

DISCUSSION

Mellisa A. Pynnonen et al. in 2007¹⁵ conducted a randomized control

trial to determine if isotonic sodium chloride nasal irrigations are more effective than saline nasal spray at improving quality of life and decreasing medication use in CRS patients. Compared to this study, our study used hypertonic saline solution to increase the efficacy of the solution and studied change in symptom frequency, severity and signs besides improvement in quality of life. Melissa A. Pynnonen followed the patients for 8 weeks, our study followed the patient for 12 weeks after treatment. Rabago D, Mundt M et al. in 2002¹⁴ used hypertonic saline nasal irrigations to see improvement in sinus symptoms and quality of life in adult subjects while our study included children, adults and elderly, thus removing the age bias and studied change in symptom frequency and signs beside symptom severity and improvement in quality of life.

Rabago D, Barrett B et al. in 2006¹⁶ assessed attitudes regarding use of hypertonic saline nasal solution (HSNI) for frequent rhinosinusitis and chronic sinonasal symptoms in 28 participants while our study included 56 patients in various groups.

Saline solutions of variable strengths that are used in nasal irrigation work by reducing inflammation through osmosis. Nasal irrigation flushes out thickened mucus that cannot be handled by the cilia, thereby, improving mucociliary clearance and also removing infected material¹⁸ but high concentrations of salt have even resulted in damage to ciliary cells¹⁹. Hypertonic saline is said to have a mild vasoconstrictive effect²⁰ and antibacterial property²¹. Different strengths of hypertonic saline have been used in various studies and ranged from 2.7%-7%. The concentration of 3.5% saline solution was chosen in our study because it was considered to be harmless and better tolerated by the patients.

In our study, symptoms and signs were scored before and after MMT, MMT with saline nasal irrigation and MMT with anuloma viloma exercises at 3, 6 month using VAS, SNOT-20, GLOBAL QUESTION, RSDI, nasal endoscopy, CT scan.

Ragab SM, Lund VJ, Scadding G in 2004¹⁷ included 90 patients of CRS who underwent pre and post treatment assessment (6 months and 1 year) of VAS, SNOT-20, acoustic rhinometry, saccharine clearance time and nasal endoscopy while our study used six scoring VAS, SNOT-20, GQ, RSDI, nasal endoscopy and CT scan, and followed patients at a frequent interval, which increased the sensitivity of our study. Ragab SM et al found there was 49.7% and 58.7% improvement in VAS and endoscopy respectively after 6 months of medical treatment compared to this we found 85.87% and 80.94% improvement in VAS and endoscopy after 6 months of medical treatment.

Melissa A. Pynnonen, Shradha S. Mukerji et al. in 2007¹⁵ included 127 patients assigned to isotonic saline irrigation and isotonic saline spray groups. All patients underwent assessment of symptom severity by SNOT-20 and the symptom frequency by Global question pre-treatment and post-treatment at 2 weeks, 4 weeks and at 6 weeks while we assessed patient using six scoring and followed patients at 3 months and 6 months which added better assessment of the study. Melissa A. Pynnonen et al found that there was 60.01% and 61% improvement in SNOT-20 and Global question scores in saline irrigation group after 8 weeks while we found 79.64% and 52.7% improvement in SNOT-20 and Global question respectively which showed a statistical significant difference ($p < 0.05$) in saline nasal irrigation thus proving its role in reducing sino nasal symptom severity and frequency.

Rabago D, Zgierska A, Mundt M et al. in 2002¹⁴ assessed 76 patients using Medical Outcomes Survey Short Form (SF-12), RSDI, and Single-Item Sinus-Symptom Severity Assessments (SIA) pretreatment and posttreatment at 1.5, 3 and 6 months and found statistically significant difference ($p < 0.05$) between RSDI scores of case and control groups at 3 and 6 months. Compared to this we also found statistically significant difference in RSDI scores between patients taking MMT and patients taking MMT with saline nasal irrigation at 3 and 6 months thus proving the role of saline nasal irrigation at improving the quality of life in CRS.

In our study the VAS and SNOT-20 showed statistically significant difference in favour of patients taking MMT and saline nasal irrigation to patients taking MMT with anuloma viloma exercises

at both 3 months and 6 months, thus proving that saline nasal irrigation is better than anuloma viloma exercises at improving the change in symptom severity in patients with CRS and patients who came for follow-up at 3 month had the response to the treatment and it persisted at 6 month follow-up. There was no recurrence, so we can say that a 3 month therapy is sufficient.

Our study also found statistically significant difference ($p < 0.05$) in RSDI scores in favour of patients taking MMT with anuloma viloma exercises to patients taking MMT with saline nasal irrigation at both 3 months and 6 months thus proving that anuloma viloma exercises are better than saline nasal irrigation at improving quality of life in patients with CRS.

In our study the Global question scores and RSDI scores found statistically significant difference in favour of patients taking MMT with anuloma viloma exercises at both 3 months and 6 months thus proving a definite role of anuloma viloma exercises at improving the change in symptom frequency and quality of life in patients with CRS.

This also proves that if we use MMT with saline nasal irrigation with anuloma viloma exercises in the management of CRS it will not only improve the symptom severity, symptom frequency and sign score but also the quality of life of the patients.

There is no study in current literature that compares the role of both saline nasal irrigation and anuloma viloma exercises as an adjunct to MMT in CRS, hence this formed the basis of our study and we compared the *adjunctive role of saline nasal irrigation and anuloma viloma exercises to maximal medical therapy* in patients of CRS.

CONCLUSION

Saline nasal irrigation and Anuloma viloma exercises are effective in CRS as an adjunct to MMT. MMT with Anuloma viloma exercises improves quality of life in CRS better than the MMT with saline nasal irrigation or MMT alone. A 3 month course is sufficient. Improvement is sustained at 6 month follow up after cessation of treatment. Our study recommends a combination of both MMT and hypertonic saline irrigation with anuloma viloma exercises at improving the symptom severity, symptom frequency, sign scores and quality of life in patients of CRS.

DECLARATIONS

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Conflict of interest: no

Ethical approval: yes

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