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Review Article

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PRESCRIPTION GUIDE OF COMMONLY AVAILABLE PEDIATRIC FLUORIDATED DENTRIFICES IN INDIAN MARKET

[1]Dr. Akanksha Garg, Dr. Priyanka Goswami and Dr. Shivam Katyal*

[1]Department of Pedodontics and Preventive Dentistry, Post graduate student, Inderprastha Dental College and Hospital, Sahibabad.
[2]Department of Pedodontics and Preventive Dentistry, MDS, Inderprastha Dental College and Hospital, Sahibabad.
[3]Department of Prosthodontics and Crown & Bridge, MDS, Inderprastha Dental College and Hospital, Sahibabad.

***Corresponding Author: Dr. Shivam Katyal**
Department of Prosthodontics and Crown & Bridge, MDS, Inderprastha Dental College and Hospital, Sahibabad.

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ABSTRACT

This article highlights fluoride containing toothpastes widely used in India and their consumption by children in accordance to their age and weight. Toothpastes are one of the commonly used carriers for providing topical fluoride therapy for the prevention of dental caries. In many countries, the use of fluoridated toothpastes was thought to be the primary reason for improved oral health of population in growing age. Although, fluoridated toothpastes are known for making enamel resistant to caries, but its misuse/overuse by children is particularly considered to be a major concern as it is known to cause dental fluorosis. Hence, an optimum level and amount of toothpaste should be used to get the maximum benefits while minimizing the risk of dental fluorosis. This article summarizes the optimal level of fluoridated Indian toothpastes to be used by children of different age and weight.

INTRODUCTION

Following the periodontal disease, caries is the second most common dental condition which occurs when the equilibrium of demineralization and re-mineralization of the dental hard tissue is imbalanced due to the influence of microbial action and various other factors.[1-3] Fluoride therapy is known for reducing the prevalence and severity of dental caries. *Dean in 1930s*, suggested that the optimum level of fluoride therapy must be able to provide the maximum protection against caries, with minimum chances of causing dental fluorosis. The "optimum" daily intake of fluoride that is considered normal for children is 0.05–0.07 mg per kilogram bodyweight, which is empirically determined and is accepted worldwide. In late 1960s, various researches concluded that fluoride can successfully be incorporated into toothpastes and their effectiveness was accessed by numerous clinical trials. Almost all toothpastes contained fluoride, by the end of the 1970s.[4] Fluoride has several caries-protective mechanisms of action. Topically, low levels of fluoride in plaque and saliva inhibit the demineralization of sound enamel and enhance the remineralization of demineralized enamel. It also inhibits dental caries by affecting the metabolic activity of cariogenic bacteria.[5] It is released when the pH drops in response to acid production and becomes available to remineralize enamel or affect bacterial metabolism.[6] It was earlier thought that, fluoride's primary action was to inhibit dental caries when incorporated into developing dental enamel (i.e., the systemic route), but the fluoride concentration in sound enamel does not fully explain the marked reduction in dental caries. It is oversimplification to designate fluoride simply as systemic or topical. Fluoride that is swallowed, such as fluoridated water, dietary supplements and fluoridated toothpastes, may contribute to a topical effect on erupted teeth (before swallowed, as well as a topical effect due to increasing salivary and gingival crevicular fluoride levels). Additionally, elevated plasma fluoride levels can treat the external surface of completely mineralized, but unerupted, teeth topically. Similarly, topical fluoride, that is swallowed also has systemic effect. Several studies have confirmed that use of fluoridated toothpaste effectively reduce incidence of dental caries, and, the demineralization of enamel is inversely correlated with the concentration of fluoride in toothpaste in both permanent or deciduous enamel, as well as root dentin.[7,8]

Although fluoridated toothpaste has certain anti-cariogenic effect, excessive ingestion might lead to adverse effects such as skeletal and dental fluorosis.[9,10] In addition, studies have concluded that the accidental swallowing of fluoridated toothpaste by children may be 2–3 times more than the safe limit, suggesting it's use as a risk factor for dental fluorosis.[11,12] Therefore, the risks of careless use of fluoridated toothpaste must not be ignored, the benefits and risks of using fluoridated toothpaste are still needed to be properly assessed.

Fluoride and Toothpaste

The discovery of the anti-caries effect of fluoride lead to a new method for reduction of caries. Fluoride works by forming a reservoir of calcium fluoride or can be incorporated in enamel to form flurohydroxyapatite (HA), which re-mineralizes early enamel caries.[1,13] The crystals of flurohydroxyapatite makes the enamel more stable.[14] Calcium fluoride can store fluoride ions in neutral or lower PH conditions and release fluoride ions, so as to increase the concentration of ions in the demineralization center and reduce or even control the demineralization of enamel. The formation of calcium fluoride on the surface of the enamel can persist for a long time. When the pH of the tooth surface decreases to less than 6, the calcium fluoride releases fluoride ions, and finally form HA, which promotes re-mineralization.[15] Fluoridated toothpaste is made by adding sodium fluoride monofluorophosphate, stannous fluoride, and other fluoride compounds. It improves the level of fluoride in the oral cavity and the surface of teeth, which can persist for more than 10 h after brushing.[16] Sufficient evidence-based studies and researches have shown that using fluoridated toothpaste is an efficient means to prevent dental caries.[17]

Overdose of Fluoride

Wright et al., reported that excessive use of fluoridated toothpaste may lead to fluorosis if it exceeds the safe limit. Therefore, it was concluded that there were certain risks in the use of fluoridated toothpaste in children.[18] *Marinho et al*., also found that children swallow 30~50% of the total amount of toothpaste when brushing their teeth, and the amount of swallowing is positively correlated with the amount of toothpaste used.[19,20] The swallowing reflex of children under 3 years old is not fully developed, so the amount of toothpaste involuntarily swallowed was high and can easily lead to fluorosis. Fluoride intake can induce serious adverse effects on the psychological and physical development of children,[21] therefore, the risks of using fluoridated toothpaste outweigh the benefits in children under 3 years old.

Fluoride Toothpaste Recommendadtion

Use of a pea-sized amount of fluoride toothpaste is recommended for children from 2 to 6 years of age.[22] Others recommend the use of a "smear" of fluoride toothpaste (approximately 0.1 gram of tooth-paste or 0.1 milligram of fluoride) for children younger than 2 years and a pea-sized amount (approximately 0.25 g toothpaste or 0.25 mg fluoride) for children from 2 to 6 years of age.[23] The optimal dose of fluoride that can be ingested is 0.05 mg per kilogram per day.[15] Pea-sized amount of toothpaste contains more than double the quantity of fluoride when compared to smear layer of tooth paste **(Table 1)**. For example, an average 2-year-old child who weighs 15 kg, brushes his or her teeth twice a day with a smear of toothpaste and swallows all of the toothpaste would ingest 0.2 mg of fluoride, resulting in a dose of 0.013 mg/kg. If this same child were to brush twice per day with a pea-sized amount of toothpaste and swallow all of the toothpaste, he or she would ingest 0.5 mg fluoride, resulting in a dose of 0.033 mg/kg.[24] Children are also exposed to fluoride through consumption of food and beverages. Considering these additional potential sources of fluoride intake and the risk of developing fluorosis at the time of tooth formation, the council recommends use of a smear of toothpaste from eruption of the first tooth to age 3 years followed by use of a pea-sized amount for children aged 3 to 6 years **(Table 2)**. This regimen is intended to maximize the caries-preventive benefits of fluoride while reducing the risk of fluorosis. Recommended dose of fluoridated tooth paste for all age groups are described in **Graph 1 and 2**. Although the risk of developing fluorosis in the permanent dentition is associated with fluoride exposure beginning at 1 year of age, the risk to the permanent central incisors is greatest at approximately 2 years of age.[25] The regimen described previously is consistent with the schedule and dosage used for prescription fluoride supplements recommended for children who have a high risk of developing caries and who live in areas without fluoridated water. The supplement dosage increase goes into effect at age 3 years; previously, an increase in fluoride supplement dosage was recommended at 2 years of age.[26] The recommendation was modified to 3 years of age to reduce the risk of developing dental fluorosis. For children at high risk of developing caries whose primary water supply contains less than 0.3 parts per million fluoride, the recommended systemic dietary fluoride supplementation is 0.25 mg (for children aged 6 months to 3 years) and 0.5 mg (for children aged 3 to 6 years).[26]

So, the recommended amount of fluoridated toothpaste according to various age group of children in Indian population various from rice grain, pea sized and half head. **(Table 3A, 3B).**

Table 1: Indian Fluoridated Toothpaste for Children.

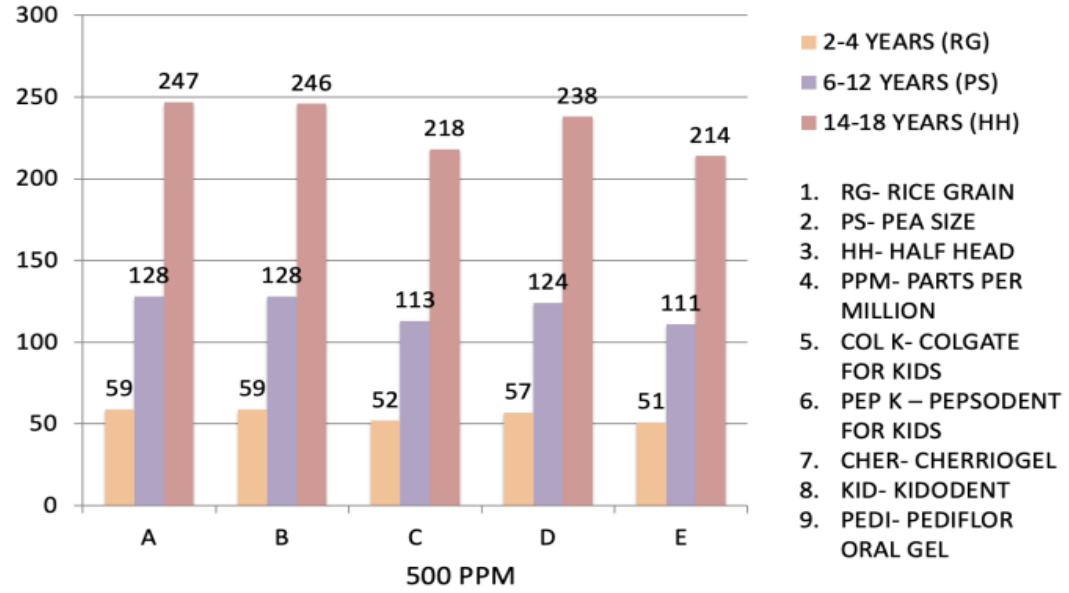
S. NO	CODE	CONCENTRATION OF FLUORIDE	CONCENTRATION OF FLUORIDE AVAILABLE		
			RG (0.1 gm) 2-4 YEARS 22-29 kgs	PS (0.25 gm) 6-12 YEARS 37-83 kgs	HH (gm) 14-18 YEARS 92-95 kgs
1	COL K	500 PPM	59	128	247
2	PEP K	500 PPM	59	128	246
3	CHER	500 PPM	52	113	218
4	KID	500 PPM	57	124	238
5	PEDI	500 PPM	51	111	214
6	COL 12	1000 PPM	158 8-14 y	306 16- 18 y	
7	PEP	1000 PPM	124 6-12 y	239 14-18 y	
8	CLO-UP	1000 PPM	121 6-10 y	233 12-18 y	
9	SENS	1000 PPM	107 6-10 y	206 12-18 y	

Table 2: Regimen Followed By Different Age Groups Based On Weight In Indian Population.

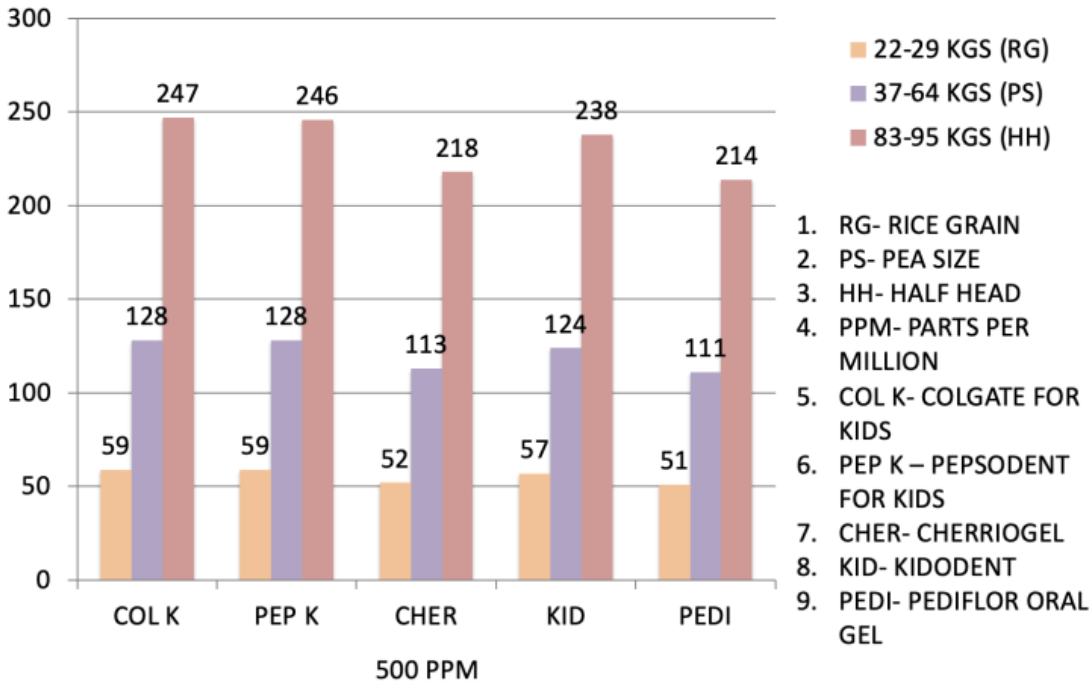
CONC OF FLUORIDE	AGE →	2	4	6	8	10	12	14	16	18
	WEIGHT →	22	29	37	45	53	64	83	92	95
	CODE ↓									
500 PPM	COL K	RG	RG	PS	PS	PS	PS	HH	HH	HH
500 PPM	PEP K	RG	RG	PS	PS	PS	PS	HH	HH	HH
500 PPM	CHER	RG	RG	PS	PS	PS	PS	HH	HH	HH
500 PPM	KID	RG	RG	PS	PS	PS	PS	HH	HH	HH
500 PPM	PEDI	RG	RG	PS	PS	PS	PS	HH	HH	HH
1000 PPM	COL 12	-	-	-	RG	RG	RG	RG	PS	PS
1000 PPM	PEP	-	-	RG	RG	RG	RG	PS	PS	PS
1000 PPM	CLO-UP	-	-	RG	RG	RG	PS	PS	PS	PS
1000 PPM	SENS	-	-	RG	RG	RG	PS	PS	PS	PS

1. **RG- RICE GRAIN**
2. **PS- PEA SIZE**

3. **HH- HALF HEAD**
4. **PPM- PARTS PER MILLION**
5. **COL K- COLGATE FOR KIDS**
6. **PEP K – PEPSODENT FOR KIDS**
7. **CHER- CHERRIOGEL**
8. **KID- KIDODENT**
9. **PEDI- PEDIFLOR ORAL GEL**
10. **COL 12- COLGATE TOTAL 12**
11. **PEP- PEPSODENT**
12. **CLO-UP- CLOSE UP**
13. **SENS- SENSODINE**



Graph 1: Recommended Amount Of Fluoridated Tooth Paste Accoring To The Age Of Child.



Graph 2: Recommended Amount Of Fluoridated Tooth Paste According To Weight Of The Child.

Table 3a: Table Showing Cld And Std Of Amount Of Toothpaste According To Child's Age And Weight.

AGE	WEIGHT	CRITICAL LETHAL DOSE	SAFETY TOLERATED DOSE	RECOMMENDED AMOUNT OF TOOTHPASTE		
				RG	PS	HH
2	22	320	80			
4	29	422	106			
6	37	538	135			
8	45	655	164			
10	53	771	193			
12	64	931	233			
14	83	1206	301			
16	92	1338	334			
18	95	1382	346			

Table 3b: Recommended Amount Of Fluoridated Toothpaste Accoring To Age Of Child.

AGE	RICE GRAIN	PEA SIZE	HALF HEAD
2-4 YEARS			
6-12 YEARS			
14-18 YEARS			

DISCUSSION

Although the risk of developing fluorosis in the permanent dentition is associated with fluoride exposure beginning at 1 year of age, the risk to the permanent central incisors is greatest at approximately 2 years of age.[27] The toothpaste regimen described previously is consistent with the schedule and dosage used for prescription fluoride supplements recommended for children who have a high risk of developing caries and who live in areas without fluoridated water. The supplement dosage increase goes into effect at age 3 years; previously, an increase in fluoride supplement dosage was recommended at 2 years of age.[28] The recommendation was modified to 3 years of age to reduce the risk of developing dental fluorosis. For children at high risk of developing caries whose primary water supply contains less than 0.3 parts per million fluoride, the recommended systemic dietary fluoride supplementation is 0.25 mg (for children aged 6 months to 3 years) and 0.5 mg (for children aged 3 to 6 years).[29] Recommending fluoride therapy in children—whether it be fluoride supplements, toothpaste or professional topical applications—typically is tied to caries risk assessment, with fluoride therapies recommended for children who are at high risk of developing caries. All children should undergo a caries risk assessment before their dentists make recommendations associated with preventing or controlling dental caries. This is a critical step in developing a personalized prevention plan. It also is critical that the dentist assess a child's total fluoride exposure from all sources (beverages, food, toothpaste, supplements, topical applications and so forth) when developing a preventive treatment plan that is directed at optimizing caries control and safety. To address the risks and benefits associated with fluoride toothpaste use in young children adequately, the dentist should aim in conversations with caregivers to assess a child's total fluoride exposure on the basis of all potential sources. There are no validated caries risk assessment tools with known sensitivity and specificity for children. This makes it challenging to base therapeutic recommendations on the risk of future disease development.[30] Evaluation of caries risk assessment tools in adults that are validated has shown that the tools

are not highly accurate in predicting future disease development.[31,32] The best predictor of a person's developing dental caries in the future is the presence of dental caries. Because most 1-year-old children do not have dental caries, and considering the rate of caries progression, it is difficult to predict which of these children will become the approximately 40 percent of children who experience dental caries in their primary teeth.[33,34] Therefore, considering the best available evidence and the continued high caries rate in children, the Council recommends the following:

- For children younger than 3 years, caregivers should begin brushing children's teeth as soon as they begin to come into the mouth by using fluoride toothpaste in an amount no more than a smear or the size of a grain of rice. Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to ensure that they use the appropriate amount of toothpaste.
- For children 3 to 6 years of age, caregivers should dispense no more than a pea-sized amount of fluoride toothpaste. Brush teeth thoroughly twice per day (morning and night) or as directed by a dentist or physician. Supervise children's brushing to minimize swallowing of toothpaste.
- It is especially critical that dentists provide counseling to caregivers that involves the use of oral description, visual aids and actual demonstration to help ensure that the appropriate amount of toothpaste is used.

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