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Development of a standardized method for comparing fluoride ingested from toothpaste by 1.5–3.5-year-old children in seven European countries. Part 1: Field work

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Abstract – *Objectives:* To develop a standardized method for measuring the variables affecting fluoride ingestion from toothpaste in young children between the ages of 1.5 and 3.5 years, and to use the method at seven European sites. *Methods:* Random samples of children were invited to take part in the study. Parents who gave consent were visited at home. The children brushed their teeth using the toothpaste brand and toothbrush type currently in use. Variables measured were: type of toothpaste used, fluoride concentration of toothpaste used, weight of toothpaste used, frequency of brushing and body weight of the child. *Results:* It was not possible to follow the agreed protocol in all seven countries and in three countries appropriate alternative methods were employed. There was considerable variation between countries in the variables investigated. Use of children's toothpaste ranged from 69% in Ireland to 98% in Portugal. In the Netherlands up to 60% of the children were using toothpaste containing <400 ppm F and in Finland up to 27% of children were using toothpaste containing >1200 ppm F. Over half of the children used <0.25 g of toothpaste per brushing and the majority of children brushed once or twice per day. *Conclusion:* Although adherence to the agreed protocol was not possible at all study sites there was a clear picture of considerable variation in the oral hygiene practices of young children throughout Europe.

Fluoridated toothpaste is considered to be the one preventive measure common to all countries showing a marked decline in caries (1) and, since its introduction in Europe during the 1970s, now commands over 95% of the toothpaste market. The cumulative anticaries benefit from using fluoridated toothpaste, as measured by the DMFS index, is reported to be about 6% for every 500 ppm F over 1000 ppm (2, 3).

The protective action of fluoride toothpaste is principally topical and therefore the ingestion of fluoride from toothpaste by young children merits consideration, particularly as the time at which the aesthetically important teeth are developing coincides with the time at which children are most likely to swallow toothpaste during toothbrushing (4). In 1977 the European Commission set the upper limit of fluoride concentration in toothpaste at 1500 ppm

for European sales over-the-counter, to comply with the therapeutic principle of providing adequate benefit with acceptable risk. The concentration of fluoride in toothpaste available without prescription in the UK has been reported to range from 0.4 to 1.5 mg F/g of toothpaste (400–1500 ppm F) (5). Toothpaste manufacturers have introduced lower fluoride toothpastes for young children, prompted in part by concerns about fluoride ingestion from toothpaste being linked with an anecdotal increase in the prevalence of fluorosis (6). Whilst a dose–response relationship between fluoride concentration and anticaries benefit exists, the effectiveness of toothpastes with less than 500 ppm F is unproven to date (7–9).

Clearly a balance between 'adequate benefit' and 'acceptable risk' for consumers must be defined and refined as the needs of the population evolve. Many studies on toothpaste use and fluoride ingestion from toothpaste have been carried out since the 1970s (10–23).

Toothpaste use has been expressed as g/day (17) and g/brushing (10–15, 18, 19, 24, 25). Ingestion data have been expressed as mg F/day (10, 12, 14, 15) or mg F/brushing (11, 13, 18, 25) and mg F/kg body weight (10, 16, 20). Consequently, comparisons between papers are difficult and trends are difficult to determine, particularly when brushing frequency is not reported. In view of recent claims that the prevalence of fluorosis is increasing, the need to express fluoride ingestion as a function of body weight (F/kg body weight) can only be emphasized.

There are few epidemiological data collected from multiple study sites using standardized methods to show how much fluoride young children ingest from toothpaste. As the characteristics of fluoride absorption from toothpaste may differ from those of fluoride absorption from food, the factors governing fluoride ingestion from toothpaste merit further study (24). Such research is important for two reasons: (i) to help manufacturers of toothpaste maintain the anticaries properties of the toothpaste at a level where the benefits are optimized and the risks are minimized; and (ii) to enable the development of relevant, clear health education messages.

The overall aim of 'Project FLINT', was to address this gap in current knowledge (26). The aim of this aspect of the project was to develop a standardized epidemiological method for collecting information for young children on individual variables that may affect fluoride ingestion from toothpaste. Such

variables included: type, fluoride concentration and weight of toothpaste used, frequency of brushing and body weight of the child. A further aim was to compare these data, collected using the standardized methodology, from sites in seven European Union (EU) countries.

Materials and methods

Subject selection

The participating study sites were: Almada/Setubal (Portugal), Athens (Greece), Cork (Ireland), Haarlem (the Netherlands), Knowsley (UK), Oulu (Finland), and Reykjavik (Iceland). Ethical approval to conduct the study was obtained locally. To study children in each of two age groups, 1.5–2.5 years and 2.5–3.5 years, the sampling frame was defined as births registered within each state in the appropriate period between 1994 and 1996. In Knowsley the local ethics committee denied the research team access to the birth registers. A satisfactory, yet comparable, alternative sampling frame was achieved by obtaining dates of births of children registered with family medical practitioners in the defined study area.

Local knowledge of death rates, anticipated compliance, tooth-brushing habits and other such factors were used to estimate the necessary size of the initial sample to yield 100 complete study cases for each age group. An invitation letter was sent to randomly selected families to outline the study and to inform them that they would be contacted again to explain more about the study and to obtain their consent to participate.

It was not possible to follow the standard selection procedure in Athens. Instead, children attending the outpatient department of the local paediatric hospital were invited to take part in the study. All participants were given a standard toothbrush and were allowed to select from the most common toothpastes on the Greek market. The questionnaire details, toothpaste use and toothpaste ingestion measures followed the protocol, but the week-long measure of toothpaste use was omitted. In Ireland, the State did not permit access to the addresses of single-parent families.

Training research personnel

Research personnel were trained in the agreed methodology at the project-coordinating centre in Cork. Videos of the methodology were also available for reference.

Telephone questionnaire

Parents were telephoned to obtain details of their child's oral health-care habits, including the toothbrush and toothpaste in current use. Any child found to brush less than once weekly was then excluded. The loss was 2% or less for all areas except Oulu where the figure was 21%. The majority of the losses were children not brushing at all.

Toothpaste use and oral-health care habits

A toothbrush and two tubes of toothpaste were purchased, identical to those described by the parent as being in current use by the child.

Two methods were employed for determining toothpaste use. Each tube of toothpaste was weighed before use to ± 0.01 g. During a home visit toothbrushing was observed using the toothbrush and one of the preweighed tubes of toothpaste provided by the research worker. The toothpaste tube was then re-weighed and the amount of toothpaste applied at the time of toothbrushing was calculated. The amount of applied fluoride was calculated from the laboratory determination of the fluoride content in the toothpaste and the weight of the toothpaste dispensed (27). The second tube of toothpaste was left with the family for sole use by the child during the following 7 days. Parents were given a form to record frequency of toothbrushing during this period and were also asked to record unintended use of toothpaste by others, losses of toothpaste and failure to use the toothpaste supplied. They were provided with a prepaid envelope to return the toothpaste and the form. The toothpaste tube was then re-weighed and the mean amount used per brushing was calculated using the recorded brushing frequency data.

Pre- and post-toothbrushing questionnaires were used to collect data on oral health-care habits. Observations were made by the researcher during toothbrushing. Each child was weighed and his/her height determined.

Statistical analysis

Pearson's correlation coefficient for paired values of measures of toothpaste use was determined and the results of the two different methods for measuring toothpaste use were compared using analysis of variance (ANOVA). Bodyweights were also compared using ANOVA.

Results

Telephone contact was made with parents of 4–12% of the child population at the six study sites (i.e.

excluding Athens). The acceptance rate ranged from 74% in Haarlem to 96% in Reykjavik. The percentage of families taking part in the study ranged from 3 to 9% of the total eligible population.

As a result of errors with protocol adherence, some data were collected from children who fell outside the two defined age groups. Data for seven children who were under 1.5 years old were excluded from the analysis but those for children over the age of 3.5 years (maximum 4.6 years) are included as a separate group.

The data used for analysis pertain to children who used toothpaste that was reported to be identical to their usual brand, for whom there were no toothpaste losses, and for whom the reported brushing frequency was at least once per week. A total of 1345 homes were visited of which there were useful data from 1094.

Types of toothpaste used

Toothpastes were classified as children's based on packaging, wording and flavouring. Toothpastes promoted as desensitizing agents, whitening agents, polishing agents and herbal were classified as specialist products. Otherwise fluoride toothpastes were classified as regular toothpastes. There was considerable variation between the study sites regarding the types of toothpaste purchased for children (Fig. 1). In Almada/Setubal, Athens and Haarlem over 90% of the parents purchased toothpaste marketed for children, whereas in Cork this proportion was only 69%.

Fluoride concentration of toothpaste used

Table 1 summarizes the frequency distribution of toothpaste use according to the fluoride concentration printed on the tube. Between 0% (Cork and Knowsley) and 60% (Haarlem) of children between
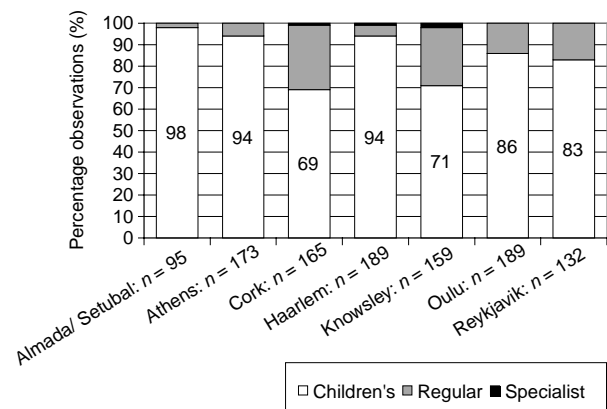

Fig. 1. Distribution of toothpastes by type as used by children between 1.5 and 4.6 years old in seven European study sites.

1.5 and 2.5 years old, and between 0% (Cork) and 45% (Haarlem) of children between 2.5 and 3.5 years old, were using toothpaste with a fluoride concentration of less than 400 ppm.

Weight of toothpaste used

Of the parents interviewed, 20% (218 out of 1094) reported that they had been advised to use an amount of toothpaste equivalent to a 'smear', 'pea-sized', or 'the smallest fingernail'. There were regional variations: a minority of parents in Cork (4%), Knowsley (7%), Reykjavik (15%), Haarlem (10%), and Athens (2%) reported that they had received such information. Conversely, in Oulu and Almada/Setubal the proportion of informed parents was much higher at 39% and 46%, respectively. Accurate weight data were obtained for 1086 out of the potential 1094 tubes of toothpaste. Between 0% (Almada/Setubal) and 77% (Oulu) of children aged 1.5–2.5 years used the recommended amount of 0.25 g (23) of toothpaste or less during the home visit (Table 2). When the mean weight of toothpaste used was calculated over a week, the regional variations remained but the percentage of children using 0.25 g of toothpaste or less decreased. A similar pattern was observed for the 2.5–3.5-year-olds. Between 7% (Almada/Setubal) and 55% (Oulu) of children used 0.25 g of toothpaste or less during the home visit, whereas over a week the corresponding values ranged from 0% (Almada/Setubal) to 43% (Oulu).

In the majority of cases, the mean amount of toothpaste used per brushing was greater when using the average measured over 1 week. Pearson's correlation coefficient for paired values of the two measures of toothpaste amount, after logarithmic transformation of the data, was 0.65 ($P < 0.0001$).

There was a highly statistically significant difference between the two methods (ANOVA, $P < 0.0001$). There was also a highly significant difference in toothpaste use by age group ($P < 0.003$). The differences in response between the age groups were the same for both methods ($P > 0.90$). The difference between the methods was not consistent across the countries ($P > 0.35$).

Reported toothbrushing frequency

With the exception of Athens, the majority of children (79%) reported brushing once or twice per day (Table 3). In Athens between 29% and 38% reported brushing a few times per week. Brushing frequency was reported to be twice a day for more than 63% of the children between 1.5 and 2.5 years old from Almada/Setubal, Haarlem and Knowsley. However, for the children between 2.5 and 3.5 years old, those brushing twice per day fell to 40% in Almada/Setubal but barely changed in Haarlem and Knowsley. In Cork the proportions brushing once or twice per day were more evenly distributed.

Body weight

ANOVA of mean body weight showed that there was an overall difference across the three age groups, in the expected direction. Body weight differed across countries ($P < 0.0025$) but differences were not consistent across the three age groups. Children from Reykjavik in the age groups 1.5–2.5 years and 2.5–3.5 years were on average the lowest in body weight compared with all the other children in the study.

Table 1. Percentage distribution of children who use fluoride toothpastes at various concentrations, as printed on the toothpaste tubes

Age group	Labelled (ppm F)	Almada/ Setubal	Athens	Cork	Haarlem	Knowsley	Oulu	Reykjavik
1.5–2.5 years		$n = 29$	$n = 28$	$n = 49$	$n = 89$	$n = 49$	$n = 60$	$n = 23$
	0 to <400	38	21	0	60	0	8	30
	400 to <800	17	11	51	34	76	5	26
	800 to <1200	45	68	33	2	14	67	43
	≥1200	0	0	16	4	10	20	0
2.5–3.5 years		$n = 57$	$n = 66$	$n = 98$	$n = 71$	$n = 72$	$n = 103$	$n = 65$
	0 to <400	11	14	0	45	1	8	9
	400 to <800	23	12	59	51	71	4	34
	800 to <1200	63	70	28	3	11	72	51
	≥1200	4	5	13	1	17	17	6
> 3.5 years		$n = 9$	$n = 79$	$n = 18$	$n = 22$	$n = 37$	$n = 26$	$n = 44$
	0 to <400	0	15	0	50	0	0	5
	400 to <800	44	14	56	45	51	4	25
	800 to <1200	56	68	39	5	32	69	68
	≥1200	0	3	6	0	16	27	2
Total	1094	95	173	165	182	158	189	132

Table 2. Mean weight of toothpaste used and percentage of children using <0.25 g of toothpaste by age group and measurement method for each study site

Study site	Measurement method	1.5–2.5 years			2.5–3.5 years			>3.5 years		
		n	% using <0.25 g	Mean weight g (SD)	n	% using <0.25 g	Mean weight g (SD)	n	% using <0.25 g	Mean weight g (SD)
Almada/	Home visit	29	0	0.47 (0.10)	57	7	0.39 (0.10)	9	22	0.44 (0.15)
Setubal	Mean 1 week	1	0	0.43 (0.00)	7	0	0.49 (0.15)	1	0	0.31 (0.00)
Athens[a]	Hospital	28	50	0.38 (0.43)	66	33	0.44 (0.33)	79	20	0.57 (0.37)
	Mean 1 week	0			0			0		
Cork	Home visit	47	32	0.39 (0.27)	96	32	0.42 (0.26)	18	22	0.46 (0.26)
	Mean 1 week	45	18	0.52 (0.30)	91	14	0.71 (0.63)	18	11	0.72 (0.55)
Haarlem	Home visit	90	42	0.36 (0.29)	71	30	0.54 (0.55)	21	38	0.46 (0.37)
	Mean 1 week	74	26	0.39 (0.22)	59	25	0.46 (0.27)	20	10	0.50 (0.27)
Knowsley	Home visit	47	32	0.41 (0.30)	70	26	0.42 (0.28)	37	22	0.55 (0.31)
	Mean 1 week	42	17	0.55 (0.30)	61	13	0.59 (0.39)	28	4	0.69 (0.30)
Oulu	Home visit	60	77	0.22 (0.33)	103	55	0.25 (0.19)	26	50	0.24 (0.13)
	Mean 1 week	60	70	0.25 (0.19)	103	43	0.30 (0.22)	26	35	0.65 (1, 70)
Reykjavik	Home visit	23	52	0.34 (0.24)	65	28	0.45 (0.39)	44	23	0.48 (0.29)
	Mean 1 week	17	41	0.32 (0.18)	59	12	0.65 (1, 22)	39	10	0.49 (0.23)
Combined	Home visit	324	43	0.36 (0.30)	528	32	0.41 (0.33)	234	26	0.49 (0.33)
total	Mean 1 week	239	35	0.40 (0.27)	380	23	0.53 (0.63)	132	14	0.60 (0.80)

[a]There was deviation from the protocol in Athens.

Overall, the children from Knowsley were the heaviest.

Discussion

The study was designed to investigate individual factors affecting fluoride ingestion from toothpaste in young children from seven European cities using standardized methods to facilitate comparisons between studies. Many previous studies have used cluster sampling, such as infants attending day-care centres or medical/dental centres (10–13, 15, 16, 20, 24, 25). In the present study the samples were based on random sampling from birth or doctors' registers, with the exception of Cork and Athens. The

Table 3. Reported frequency of toothbrushing expressed as a percentage of children by age group and study site

Study site (n)	Once a a week	Few times a week	Once a day	Twice a day	>Twice a day
1.5–2.5 years					
Almada/Setubal (29)	0	3	28	69	0
Athens (28)	4	29	43	21	4
Cork (49)	0	16	39	43	2
Haarlem (90)	0	1	32	63	3
Knowsley (49)	0	2	29	65	4
Oulu (60)	0	8	70	22	0
Reykjavik (23)	0	9	57	35	0
2.5–3.5 years					
Almada/Setubal (57)	0	21	39	40	0
Athens (66)	3	38	42	11	6
Cork (98)	3	10	36	48	3
Haarlem (71)	1	1	34	61	3
Knowsley (72)	0	3	25	67	6
Oulu (103)	0	6	78	17	0
Reykjavik (65)	0	5	45	49	2
>3.5 years					
Almada/Setubal (9)	0	11	44	44	0
Athens (78)	3	38	44	15	1
Cork (18)	0	11	33	50	6
Haarlem (22)	5	0	32	64	0
Knowsley (37)	0	3	27	57	14
Oulu (26)	0	15	73	12	0
Reykjavik (44)	0	7	45	48	0

acceptance rate was high. The conditions under which the parent/child were asked to brush their child's teeth were, as far as possible, close to normal, with the exception of an observer being present and the time at which they were requested to brush. Some previous studies can be criticised for asking the parent/child to brush under artificial conditions, brush in settings other than usual, use a toothpaste other than that normally used, including only children who brush by themselves, or for collecting information from questionnaires (10–15, 18, 25, 27).

Children's toothpastes

Whilst the market for children's toothpaste is relatively small (28) the results of this study showed that use is relatively high: 80% or more across all study groups except Knowsley and Cork where it was 73% and 63%, respectively. When the distribution of children using toothpastes at various fluoride concentrations was analysed, clear differences were observed between the study sites. In Oulu, 87% of children aged between 1.5 and 2.5, and 89% of children aged between 2.5 and 3.5, used toothpastes with greater than 800 ppm F. In contrast, only 24% and 28% of children in the respective age groups in Knowsley used similar toothpastes. These results indicate that although toothpaste can be described as children's this does not necessarily reflect the fluoride concentration but the flavour and packaging. In Haarlem, a high percentage of children, between 45% and 60%, used toothpaste fluoridated at less than 400 ppm F. Levy et al. (21) showed that larger quantities of toothpaste flavoured for children were used compared with the quantities of regular toothpaste.

In the UK the recommendation is that children under the age of six who are considered to be at low risk of developing caries should use toothpaste containing 600 ppm F and children in a higher risk category should use a toothpaste with 1000 ppm F (5). This apparent disparity suggests that there is no consensus across Europe as to the appropriate fluoride concentration in toothpaste for children who may swallow significant amounts.

Weight of toothpaste used

The mean toothpaste use for the 1.5–2.5-year-olds ($n = 324$) was 0.36 g (range of means was from 0.22 g for Oulu to 0.55 g for Knowsley), similar to the result obtained for a random sample of 50 children aged 2.5 years, also from the north-west of England and visited at home (29). Other data from studies on children of comparable ages give results that were outside the range of means found in our study populations. From figures given in a table on fluoride ingestion a mean of 0.16 g toothpaste used was calculated in children aged 1–2 years ($n = 15$) from Québec (12). In a study of 2-year-olds at Québec kindergartens ($n = 36$) the mean amount of toothpaste used was 0.62 g (13).

The mean toothpaste use for the 2.5–3.5 year olds ($n = 528$) was 0.41 g (range of means was from 0.25 g for Oulu to 0.54 g for Haarlem), which compares with 0.55 g ($n = 113$) reported by Dowell (19) who studied 3-year-olds from Bristol and 0.53 g ($n = 56$) reported by Naccache et al. (13). The mean toothpaste use for children greater than 3.5 years old ($n = 234$) was 0.49 g (range of means was from 0.24 g for Oulu to 0.57 g for Athens), which compares with the 0.26 g reported by Levy et al. (22) who studied 28 US preschoolers aged 40–48 months.

Even though almost half the parents in Oulu (39%) and Almada/Setubal (46%) had been instructed to use 'small amounts' of toothpaste, 61% of the children in Oulu used less than 0.25 g whereas only 6% of the Portuguese children did so (Table 2). This difference is surprising and raises a question over the phrases used to convey 'small amounts' of toothpaste and how they are communicated. The British Society for Paediatric Dentistry (BSPD) recommends that toothpaste tubes carry instructions to indicate that children under the age of 6 years should only use a 'pea-sized' amount (5). Of the 132 different brands used by the children in this study, 63 (52%) carried the recommendation to use less than a 'pea-sized' amount. There were, however, variations between the study sites. In Oulu and Haarlem, none of the purchased tubes of toothpaste conveyed this information. In Cork and Knowsley 99% and 98% of the purchased tubes conveyed this information, whilst in Athens, Reykjavik and Almada/Setubal the respective percentages were 29%, 23% and 6%. These differences are likely to reflect national differences in labelling and therefore differences in access to information on how much toothpaste should be used. Following an alternative suggestion that young children should use a 'smear' of low-fluoride concentration toothpaste (30), more recent research in the UK (29) determined how much toothpaste mothers of young children dispensed following the instruction to use either a 'pea-sized' amount or a 'smear'. A statistically significantly smaller amount of toothpaste (0.22 g) was dispensed following the instruction to use a 'smear' compared with a 'pea-sized amount' (0.30 g). The authors questioned the clinical significance of the above difference and were

cautious about recommending that parents be advised to use a 'smear' because one parent misinterpreted the advice and covered the entire toothbrush head.

Method used to determine weight of toothpaste used

Previous work has shown that the amount of toothpaste used and the amount of fluoride ingested from toothpaste varies more between children than within children (25). It was therefore decided to observe considerably larger groups than in other studies of toothpaste ingestion rather than repeat observations.

It is possible that the presence of an observer in the parental home in this study may have influenced the amount of toothpaste dispensed (31). Despite the attempts to ensure that the study design replicated 'usual conditions', it was decided that an additional alternative approach to measuring toothpaste use could be included without incurring significant additional expense. Parents were given a tube of toothpaste to use for the child for 7 days. The disadvantage of this method was that inaccurate reporting on behalf of the parent may have affected the outcome measure. In a study using a similar approach it was found that out of 179 tubes 19 were damaged on return or had been used by family members and a further seven were not returned – a success rate of 85% (17). With the exception of Almada/Setubal, the success rate in this study ranged from 84% in Haarlem to 100% in Oulu. In Almada/Setubal the success rate of 9% can only be explained by poor adherence to the protocol.

The results showed that there was a highly significant difference between the two methods for measuring toothpaste use. The correlation coefficient of 0.65 was very similar to that of 0.63 reported by Levy et al. (32) for the mean value of toothpaste used derived from a 1-week diary and observed brushing on children of a similar age group. For both methods used in the present study it could be argued that there was bias. In general, a low percentage of parents claimed to be informed that small amounts of toothpaste should be used. It is therefore difficult to conceive that the effect of being observed would systematically result in less toothpaste than normal being dispensed. On the other hand, for the diary method of determining toothpaste use it is more conceivable that there were unreported toothpaste losses and unreported toothpaste use by other family members, resulting in an overestimate of toothpaste use as measured over a week. It is possible that the true values of toothpaste use lie somewhere between the two sets of data. Studies reporting toothpaste use and fluoride ingestion from toothpaste based on observed measurements may therefore be under-reporting the true amount of toothpaste used. It would appear that further research is required into the most appropriate means of recording toothpaste used and ingested by young children.

Reported frequency of toothbrushing

There appear to be some behavioural variations in brushing frequency, notably the tendency to brush once a day in Oulu (over 70% or more across all age groups) compared with over 60% of children across all age groups brushing at least twice day in Haarlem and Knowsley. In Athens at least a third of the children across all age groups had not established a regular tooth-cleaning habit. As discussed elsewhere (10) frequency of tooth cleaning was not found to be significant for fluoride ingestion.

The development of a standardized methodology for collecting the data presented in this paper was crucial to its success but it was apparent that adherence to the protocol was not possible at all study sites. Despite this, a picture of variation in the oral-hygiene habits and practices of young children across Europe emerged, allowing comparisons between European countries for the first time.

Acknowledgements

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