

Comparison of Cold Water Sponging and Acetaminophen in Control of Fever Among Children Attending a Tertiary Hospital in South Nigeria

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ABSTRACT

Background: A wide range of childhood illnesses are accompanied by fever, leading to varied attempts at treatment by caregivers at home before coming to a hospital. Common modalities of treatment include use of antipyretics and physical methods such as cold water sponging, fanning and removal of clothing. These treatment modalities have been received with varied attitudes among physicians and the scientific community. This study was to assess the efficacy of both modalities in first-line management of fever in our area. **Objectives:** The main aim of the study is to compare the effectiveness of cold water sponging with that of oral paracetamol in the treatment of fever in children attending the University of Calabar Teaching Hospital, Calabar. **Subjects and Methods:** This is a randomized clinical trial. Eighty-eight children aged 12-120 months who presented to the Children Outpatient Clinic (CHOP) and the Children Emergency Room (CHER) of University of Calabar Teaching Hospital, Calabar, with acute febrile illness and axillary temperatures spanning ≥ 38.0 - 40.0°C . All children within the age limit whose caregivers gave consent were recruited into the study and were randomized to receive either cold water sponging or oral paracetamol. Axillary temperature, pulse rate, respiratory rate and assessment of discomforts (crying, shivering, goose pimples and convulsions) were recorded every 30 min for 2 h. The results were analyzed using the SPSS statistical software and have been presented in the tables. **Results:** Cold water sponging was very effective in temperature reduction within the first 30 min, with 29 (70.73%) having their temperature reduced to within normal limits. This declined to 12 (29.26%) at 60 min and 4 (10.53%) at 120 min, with the mean temperature differences from the baseline value following the same trends (1.63°C by 30 min, 0.91°C by 60 min and 0.39°C by 120 min). When compared with paracetamol, cold water sponging was more effective in temperature reduction within the first 30 min ($P = 0.000$), with the difference in effect at 60 min less significant between these two groups ($P = 0.229$). Paracetamol demonstrated a gradual and sustained reduction in temperature with the proportions of afebrile children in this group increasing from 7 (16.27%) at 30 min to 33 (78.57%) at 120 min. The mean temperature differences from the baseline value also showed the same trend. Children who received cold water sponging had more discomforts compared with those who received only oral paracetamol. **Conclusions:** It is concluded that cold water sponging, although producing rapid reduction in temperature compared with paracetamol, has effects that last only for a short time. Paracetamol on the other hand produces a gradual but sustained effect. The discomforts experienced should not be a limiting factor to the use of cold water sponging in reducing the body temperature of febrile children. Cold water sponging is safe and its use by mothers and primary caregivers should be encouraged while preparing to take the child to the nearest health facility for definitive treatment of the underlying cause of the fever.

Keywords: Children, cold water sponging, fever, paracetamol, temperature

Introduction

Fever is perhaps the oldest and most universally known hallmark of disease.^[1] It is a common response of the body

to infection.^[2] It is one of the commonest symptoms for which primary care physicians see children in their offices or in hospital clinics.^[3,4]

Despite the burden of fever on the healthcare services, it has been documented that there is a great disparity between the frequency of fever in clinical practice and the amount

Access this article online

Quick Response Code:



Website:
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DOI:
10.4103/2249-4863.117409

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of formal teaching devoted to its pathophysiology and management in medical schools.^[5] This may suggest that teaching and research into the management modalities for fever may not be enough, leaving the physicians in many cases unprepared to contribute in reducing the fever burden on the health-seeking population.

Treatment of fever at home prior to presentation to a hospital is a common practice in our environment and other malaria endemic sub-Saharan African countries.^[6-10] This is usually done by persons with no medical competency, which in many cases leads to complications. The treatment modalities employed include a combination of reducing clothing; exposing the child to air; tepid sponging; and using drugs such as paracetamol, anti-malarials and antibiotics.^[7,11] Others use traditional remedies such as giving home herbs, or using plain water as enema, or using drugs from home.^[12]

In many African communities febrile convulsions are said to be caused by gods or evil spirits.^[13] Arising from this belief, children with febrile convulsions are subjected to various inhumane practices as forms of home treatment, including placing the feet of some of these children over fire. Some are forced to drink palm kernel oil and other concoctions such as cow urine.^[10,11] Others are taken to the native doctor's house or to the prayer houses instead of a healthcare facility, leading to many complications, including burn injuries, aspiration pneumonia, hypoglycemia and cerebral damage from repeated and prolonged convulsion. This may contribute to later sequelae of febrile illness such as afebrile convulsions and epilepsy, with up to 5% of children with febrile seizures eventually developing afebrile convulsions or epilepsy.^[14,15]

While there is evidence that fever is an adaptive physiological mechanism with beneficial effects in fighting infection,^[4,15,16] highly elevated body temperature and or rapidly rising body temperature reaching values of 41.1°C and above exposes children to the risk of serious complications such as brain damage and febrile convulsions.^[2,17]

The immediate and late complications of fever can be reduced through simple and inexpensive methods such as cold water sponging by teaching mother and other caregivers how to apply and use them. The study set out to investigate the effectiveness of cold water sponging on the control of fever in children with febrile illness.

Subjects and Methods

This is a randomized clinical trial involving children attending the Children Emergency Room (CHER) and the Children Outpatient (CHOP) of the University of Calabar Teaching Hospital, Calabar, located in the South South region of Nigeria. The study was conducted between October 2008 and January 2009 by a team of doctors, including family physicians and pediatricians assisted by other ancillary medical staff.

All children within the age of 1-10 years brought to the Children Emergency Room (CHER) and the Children Outpatient Clinic (CHOP) with fever among other complaints that met the inclusion criteria were included in the study. Children with axillary temperature of 38.0-40.0°C, with caregivers willing to stay for up to 2 h for observation and giving informed consent, were recruited into the study. Very ill children needing emergency attention such as those with a history of febrile convulsion, severe dehydration from diarrhea, with temperature greater than 40°C, severe vomiting, or who had paracetamol within 4 h prior to presentation and those whose caregivers refused to give consent were excluded.

The minimum sample size was calculated using the formula for calculation of sample size per group, when comparing two proportions.^[18] According to the sample size theory by Gerard, when many means or proportions are compared, statisticians worry about the problem of multiple comparisons, but there are no easily accessible formulas or computer programs for basing sample size calculations on them. Consequently, the two-group sample size was used.^[19]

$$n = \frac{(Z\alpha + Z\beta)^2 \times [p_1(1 - p_1) + p_2(1 - p_2)]}{(p_1 - p_2)^2} \quad (1)$$

n = Desired sample size per group.

$Z\alpha$ = 1.96, standard normal deviation, which corresponds to the 95% confidence level.

$Z\beta$ = 0.84, which corresponds to a statistical power of 80%.

p_1 = Proportion of subjects afebrile in the paracetamol-only group after 1 h.

p_2 = Proportion of subjects afebrile in the sponging-only group after 1 h.

In a study in Ibadan comparing the efficacy of tepid sponging with that of paracetamol in reducing temperature in febrile children, out of 40 children studied in each group, 28 (70%) were found to be afebrile within the first 1 h in the paracetamol group, whereas 16 (40%) were found to be afebrile within the same period in the sponged group.^[20]

This means that the proportion of children afebrile in the first 1 h in the paracetamol group (p_1) was 0.7, whereas the proportion of children afebrile in the same period in the sponged group (p_2) was 0.4. Thus using the formula above, sample size per group (n) was calculated to be 39.2, which was approximated to 40 subjects per group and an attrition factor of 10% was added to make it 44 subjects per group. Thus for the two groups, the sample size will be 88 subjects.

Allocation sequence (randomization) and concealment were done by the researchers through balloting to reduce bias. The two modalities under study were written on separate pieces of paper by the researchers in equal numbers, such that all added up to the estimated sample size of 88. These pieces of papers were then folded, pooled together in a bag and mixed thoroughly. The

research assistant then picked the papers at random. The first paper picked was concealed by dropping it into a non-transparent brown envelope and given serial number 1; the second paper picked was also concealed likewise and given serial number 2; and so on until the last paper in the bag was picked and given the last serial number. The first patient who met the selection criteria took serial number 1 and the intervention mentioned in the envelope was given to the patient. This was continued until the desired sample size was reached. Through the above sampling method the subjects were divided into two groups A and B. Children in group-A received only cold water sponging, whereas those in group-B received oral paracetamol in a dosage of 15 mg/kg.

Equipments/materials used for the study

The materials and equipments used for the study included a mercury thermometer (Umec fever thermometer, NAFDAC No.: 03-1068), plastic buckets, a weighing scale (Harrison floor scale), a solid mass of standard weight (body sculpture) and hand towels. The Emzor brand of tablets/syrup paracetamol was used throughout the study. This is because this brand is easily accessible and fully registered by the Nigerian National Agency for Food, Drug Administration and Control (NAFDAC, reg. no.: 4-0411). This medication was provided by the researchers. Cold water was obtained from a tap, collected in a bucket and allowed to approximate the room temperature (water at room temperature). The room temperature in Calabar varied between 23.0°C and 33.0°C.^[21]

Validity and reliability testing

The instruments used in the study were validated to ensure that they gave accurate and correct measurement. A test – retest was performed to ensure consistency of measurement.

Data collection

Children who met the inclusion criteria were seen by the research team. The study was explained to the caregivers and consent was obtained. The information obtained included the age and sex of the child, the duration of the illness, ingestion of any antipyretic medicine 4 h before coming to the hospital, previous history of febrile convulsion, and history of diarrhea and vomiting amongst others. This was followed by a brief physical examination of the child. Their weight, height and presenting body temperatures were also measured and recorded. They were then randomly assigned to the different treatment groups serially by the sampling method described above.

Group-A: Cold water sponging alone

On presentation, the initial temperature, pulse and respiration (TPR) of the subjects were measured, and the readings were recorded as initial or values at 0 time in the data collection sheet. The subjects were completely undressed and then sponged with cold water from head to toe by their mother, caregiver or any of the research assistants. Sponging was done for a period of 30 min. At the end of sponging, a second TPR reading was

taken immediately. This was recorded as value at 30 min. The third readings were taken 30 min later (or 1 h from presentation), whereas the fourth reading was taken 60 min later (or 90 min from presentation). The last reading was taken 90 min later (or 2 h from presentation).

Group-B: Paracetamol alone

After measuring and recording the initial TPR values, the subjects in this group were given oral paracetamol in a dosage of 15 mg/kg, while other observations were as described above.

All subjects were observed for a period of 120 min; their body temperature, pulse and respiration were measured and recorded in the data collection sheet every 30 min. Also recorded in the data collection sheet were the outcome measures. Primary outcome included proportions of children afebrile at 30 and 60 min of observation. Secondary outcome was degree of discomfort experienced by the subject following exposure to the interventions under study or after administration of paracetamol. This was measured by noting if the subjects had any of the following: Convulsion, shivering, goose pimples and excessive crying following intervention.

Those who required further treatment were treated accordingly. Subjects who were given rescue treatment were excluded from the study and were subsequently referred to the pediatricians in the children emergency ward.

At the end of the 2-h observation period, the subjects and their parents were thanked for taking part in the study; the parents were counseled on the benefits of healthcare facility-based treatment against self-medication, and on the benefits of childhood immunization.

Data analysis

The data collected were entered into a computerized database and statistical analysis was done using SPSS version 15. $P < 0.05$ was taken to be significant. Student's t -test, analysis of variance (f -stat) and χ^2 -test were used for significant testing. Illustration of the results has been done in the tables. A child was adjudged to have fever if axillary temperature was equivalent to and above 37.5°C.

Ethical considerations

During data collection and subsequent analyses, all relevant ethical issues that are required in clinical trials were respected. In brief, the caregivers of children who were recruited into the study were informed about the purpose and procedures of the study. They were also informed about their rights as volunteers before they were asked to sign a written consent. Participation was entirely voluntary and each individual was free to leave the study at any time. Refusal to participate did not affect the care given to the child. Ethical approval was obtained from the Ethical Committee of University of Calabar Teaching Hospital, Calabar. The research was self-funded.

Results

Eighty-eight children who met the inclusion criteria were enrolled into the study. The characteristics of the children enrolled in the study are as seen in Table 1. The sponged and paracetamol groups had similar demographic characteristics at presentation. The subjects comprised 54.55% males and 45.35% females as shown in Table 2.

Table 3 shows the mean temperatures at different time points in the various groups compared with their mean presenting temperatures. The sponged group demonstrated maximum fall in mean temperature from the baseline temperature value of

38.84°C (SD, 0.65) to 37.21°C (SD, 0.92) at 30 min. No further reduction in mean temperature was noted throughout the observation period. The mean temperatures at all the observation points (37.21°C at 30 min, 37.96°C at 60 min, 38.29°C at 90 min and 38.45°C at 120 min) were below mean baseline temperature.

Table 4 shows the number of children who became afebrile during the course of the study. At 30 min, a higher number of children in the sponged group were found to be afebrile compared with those in the paracetamol group ($P = 0.000$), whereas at the 60-min observation, there were 18 children afebrile in the paracetamol and 12 children in the sponged group ($P = 0.299$). There was a progressive increase in the number of afebrile children in the paracetamol group at 90 and 120 min, rising from 26 to 33 children compared with 7 and 4 children, respectively ($P = 0.000$ in both observation points).

Table 5 compares the proportion of children rescued in the sponged group and the oral paracetamol group. There was no significant difference between the two groups in the number of children rescued during the observation period.

Table 1: Characteristics of the children in the study

Characteristic	Treatment group	N	Mean (SD)	t	df	P value
Age (months)	Paracetamol	44	36.23 (28.9)	-1.015	86	0.313
	Sponged	44	42.84 (32.1)			
Weight (kg)	Paracetamol	44	13.03 (5.1)	-1.611	86	0.111
	Sponged	44	15.4 (8.3)			
Height (m)	Paracetamol	44	0.9 (0.2)	0.079	86	0.940
	Sponged	44	0.9 (0.2)			
Temperature (°C)	Paracetamol	44	38.7 (0.6)	-0.952	86	0.344
	Sponged	44	38.8 (0.64)			
Pulse rate (beats/min)	Paracetamol	44	133.2 (16.2)	1.653	83	0.102
	Sponged	44	127.1 (18.0)			
Respiratory rate (breathes/min)	Paracetamol	44	44.8 (8.8)	0.300	81	0.770
	Sponged	44	43.9 (17.4)			

SD: Standard deviation

Table 2: Sex distribution of subjects

Treatment group	Male (%)	Female (%)	Total (%)
Paracetamol	23 (26.14)	21 (23.86)	44 (50)
Sponged	25 (28.41)	19 (21.59)	44 (50)
Total	48 (54.55)	40 (45.35)	88 (100)

Table 3: Comparison of mean temperature at different points with baseline temperature in the two groups

Treatment group	Time (min)	Baseline	30	60	90	120
Paracetamol	Participants	44	43	43	43	42
	Mean temp. (°C)	38.72	38.16	37.75	37.34	37.12
	Temp. difference		0.56	0.97	1.38	1.60
	df		76	85	85	85
	SD	0.54	0.74	0.67	0.71	0.60
	t test		4.04	7.85	10.31	13.08
	P value		0.000	0.000	0.000	0.000
Sponged	Participants	44	41	41	40	38
	Mean temp. (°C)	38.84	37.21	37.96	38.29	38.45
	Temp. difference		1.63	0.93	0.55	0.39
	df		71	83	68	80
	SD	0.65	0.92	0.80	0.94	0.83
	t test		9.41	5.60	3.11	2.39
	P value		0.000	0.000	0.003	0.019

SD: Standard deviation

Table 4: Comparison of the number of children afebrile at different time points in the two groups

Time (min)	Treatment group	No./group	No. afebrile (%)	df	χ^2	P value
30	Paracetamol	43	7 (16.27)	1	25.41	0.000
	Sponged	41	29 (70.73)			
60	Paracetamol	43	18 (41.86)	1	1.45	0.229
	Sponged	41	12 (29.26)			
90	Paracetamol	43	26 (60.47)	1	20.54	0.000
	Sponged	40	7 (17.5)			
120	Paracetamol	42	33 (78.57)	1	37.12	0.000
	Sponged	38	4 (10.53)			

**N=44 in both groups at baseline. There were four subjects rescued while the others dropped out of the study.

Table 5: Comparison of proportion of children rescued in the sponged and paracetamol groups

Treatment group	Number rescued	Not rescued	Total
Paracetamol	0	42	42
Sponging	4	38	42
Total	4	80	84

$\chi^2=2.644$, df=1, $P=0.104$, N=44 per group, Likelihood ratio, χ^2 test with Yates corrections

Table 6: Proportions of children who experienced discomfort in the various groups

Discomforts	Treatment groups				df	χ^2	P value
	Paracetamol		Sponging				
	Yes	No	Yes	No			
Shivering (%)	0	44 (100)	11 (25)	33 (75)	1	12.57	0.000
Crying (%)	2 (4.6)	42 (95.4)	14 (31.8)	30 (68.20)	1	11.0	0.001
Goose pimples (%)	0	44 (100)	1 (2.3)	43 (97.7)	-	-	-
Convulsion (%)	0	44 (100)	0	44 (100)	-	-	-

N=88 (44 per group)

A total of four children left before the end of the observation period, with two from each group.

Table 6 shows that the commonest discomfort manifested as crying in 14 (31.8%) of children followed by shivering in 11 (25%) of children in the sponged group. There was minimal manifestation of discomfort among the children that took paracetamol with only 2 (4.6%) children crying.

Shivering and crying were observed much more in the sponged group, with 11 (25%) children, compared with none in the paracetamol group ($\chi^2 = 12.51, P = 0.000$), experiencing shivering, whereas 14 (31.8%) out of 44 in the sponged group cried compared with 2 (4.6%) in the paracetamol group ($\chi^2 = 11.0, P = 0.001$). Only one child in the sponged group had goose pimples whereas none of the children in both groups had convulsion during the study.

Discussion

This study was an attempt at finding out if cold water sponging has comparable efficacy to paracetamol in reduction of body temperature of febrile children. It has been documented that the main reasons for treating fever in children are to reduce the risk of febrile convulsion and to relieve their discomfort, thereby abating their parents' anxiety.^[22] However it has not been proven that antipyretics or sponging can prevent febrile convulsions or their recurrences.^[23,24] The arguments against use of antipyretics are based on the possible role of fever in assisting body defense mechanisms, the value of fever as a diagnostic sign and the unwanted effects that may occur when antipyretics are used. Fever need not always be treated, rather the primary goal in fever management should be to find the cause of fever and start definitive treatment.

Reduction of fever with cold water sponging is widely practiced by both caregivers at home^[15] and by nurses in hospitals. However its usefulness in fever reduction is controversial.^[2] Some authors believe it is not beneficial and that it causes discomfort in children, and should be discarded.^[25]

In this study, cold water sponging was found to be very effective in lowering body temperature within the first 30 min, but much less effective for further reduction of fever after this period. Though mean temperature at 60, 90 and 120 min showed a statistically significant temperature reduction from mean baseline temperature ($P = 0.000, 0.003$ and 0.019 , respectively), clinically they were not significant, because the children were still febrile (temperature of 38.45°C). This is comparable to the findings in the paracetamol group where there was a gradual and sustained reduction in body temperature, with a temperature of 37.12°C at 120 min. This was statistically significant ($P = 0.000, 0.000$ and 0.000 , respectively). The number of afebrile children in the two groups also followed the same trend. These findings are consistent with findings in previous studies, in which sponging was found to be effective in reducing fever only within the first 30 min of observation.^[26-28] The explanation for this could be that

sponging can only lower body temperature through conduction, convection and evaporation of heat from the body surface, without affecting the thermoregulatory center or preventing the production of prostaglandin E_2 , resulting in vasodilatation, sweating, and increased heat loss and reduced heat production.^[1,29,30] On the contrary, the peak plasma concentration of paracetamol is usually reached in 30-60 min and half-life is 2-4 h at the therapeutic dose.^[31] This could be the explanation for the sustained drop in mean body temperature in the paracetamol group.

Once sponging is stopped body temperature starts rising again as was seen in the study. A study by the Sponging Study Group based in the United States of America concluded that sponging did not have any considerable effect on fever reduction at 30 min.^[25] However, in their study, sponging was done for 20 min and temperature reading was not taken immediately but 10 min after sponging was stopped. The difference in findings may be due to the methodology in which case temperature reading was done when temperature must have started rising (10 min after sponging).

Concerning comfort of the children, a significant proportion of children who were sponged experienced some degree of discomfort (shivering and crying) while sponging was going on. Thereafter they did not show any other sign of discomfort. This is similar to other studies that reported shivering and crying associated with sponging.^[26,32] This result is consistent with the findings reported in a similar study.^[27] But Agbolosu *et al.*,^[26] in another study reported that there was no significant difference in the two groups when discomforts was assessed. These discomforts pose a great challenge to the use of sponging in fever treatment and can be a major impediment, as one of the major reasons for treating fever in children is to relieve their discomfort and thereby abate their parents' anxiety.^[22] The use of a modality that may likely add to or increase discomfort may not be appreciated by the children. It is to be noted, however, that despite these discomforts sponging is widely practiced by parents at home as a first aid to reduce fever before presentation to a hospital.^[15] This may be due to the fact that many parents/mothers/caregivers would rather have their children shiver or cry than have them convulse, which in our communities is a sign of a bad omen. This also explains why during the study none of the mothers objected to sponging.

Comparing the number of children afebrile at the different points during the study, it would seem like the effect of both modalities were similar at 60 min (18 afebrile in the paracetamol and 12 in the sponged groups; $P = 0.229$) with the difference not being statistically significant. This result is consistent with the findings in previous studies comparing the efficacy of sponging versus paracetamol in reducing body temperature in febrile children.^[26-28]

The proportion of afebrile children in the paracetamol group as compared with the sponged group was also found to be lowest at 30 min. This was followed by a steady increase, with the highest proportion recorded at 120 min. Mahar *et al.*,^[32] and Kinmonth *et al.*,^[28] also reported that at 60 min a greater proportion of children who were given only paracetamol were still febrile.

Conclusion and Recommendation

This study has demonstrated that cold water sponging produces a more rapid reduction in body temperature of febrile children in a tropical environment as compared with oral paracetamol. This superior effect of cold water sponging over paracetamol is more evident while the act of sponging is ongoing. Though paracetamol produces consistent reduction of body temperature in febrile children, the effect becomes evident after about 30 min. Consequently, water sponging can be recommended as an adjunct to paracetamol in control of fever. It can also be used in the primary care of febrile children by caregivers in order to prevent convulsions before arrival at a health facility. There is need to educate all mothers, and indeed women of reproductive age and all primary caregivers on how to administer water sponging to febrile children.

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How to cite this article: Aluka TM, Gyuse AN, Udonwa NE, Asibong UE, Meremikwu MM, Oyo-Ita A. Comparison of cold water sponging and acetaminophen in control of fever among children attending a tertiary hospital in South Nigeria. J Fam Med Primary Care 2013;2:153-8.

Source of Support: Nil. **Conflict of Interest:** None declared.