Original Research Article

Effectiveness of tepid sponging along with antipyretic drug versus only antipyretic drug in the management of fever among children – A Randomized Control trial

ABSTRACT

Background: Childhood fever remains a very significant health issue among parents.A wide range of childhood illnesses is accompanied by fever, leading to varied attempts at treatment by parents at home before reaching to hospitals.Common methods of treatment include the use of Antipyretics and Physical methods like tepid sponging.These methods have created varied attitudes among community.Hence this study was conducted to assess the efficacy of both methods of treatment among children with fever.**Objectives:**To compare the effectiveness in reducing the body temperature between use of antipyretic drug versus tepid sponging with antipyretic drug.**Materials and methods:**A randomized control study was conducted for a period 18 months among 100 children of 6 months -12 years presenting with complaints of fever.The children were randomly allocated to Tepid sponging with antipyretic group and antipyretic alone group.The children were monitored for the reduction pattern of the temperature and vitals at various time intervals.The unpaired t test was used to compare means between groups and ANOVA test was used to compare means before and after intervention.**Results:**There no significant difference in reduction pattern of temperature among the groups at admission, half an hour, one and half hours and 2 hours post intervention.There is a significant reduction in temperature from baseline till 2 hours post intervention in both groups.Pulse and Respiratory rate showed the potential efficacy of proposed treatment to reduce the pyrexia.As there is gradual normalization of vitals as pyrexia beings to subside.**Conclusion:**Antipyretics was found to be one of the easier and cheaper intervention for administration when compared to physical

methods in management of fever in children.Physical method like tepid sponging can be administered along with antipyretic medications to reduce the body temperature, both at home and healthcare facility by the parents or caregivers or paramedics for better and earlier relief from fever among children who don't experience any discomfort during the procedure.

KEYWORDS: pyrexia, tepid sponging, temperature, antipyretic drug, randomized trail

INTRODUCTION

Fever is defined as the condition at which the body's temperature is raised above normal temperature due to fluctuations in the temperature regulator in the hypothalamus. The condition is the natural body's response to various stimuli, including infections or other stresses[1]. Based on the guidelines for the management of febrile illness by World Health Organization (WHO) and Society of Critical Care Medicine and the Infectious Disease Society of America (IDSA) the rectal temperature development >38ºC (100.4ºF) or the oral temperature/ ancillary temperature exceeds 37.8ºC (100ºF) or 37.2ºC (99ºF), respectively as the major indicator of fever in both adults and children. The word fever has its origin from Latin, means heat. Pyrexia rooted from Greek word and the meaning is fire or fever. Other interchangeable source for the word fever/pyrexia comes from the body temperature raised due to the action of thermoregulatory pyrogens in the hypothalamus[2]. The body temperature in the healthy individual perhaps vary with several environmental and biological parameters including, time of day, site of temperature measurement, physical activity level, sex, age, race and others. Even though, this variability occurs in those individuals, the body temperature is highly maintained within the thermal set point through the process of thermoregulation. The recent shred of scientific evidence shows that the temperature is regulated by wide spectrum of independent thermos-effector loops (each with own afferent and efferent branches). Of note, the body temperature is regulated by the thermoregulatory circuitry on dependent basis. The preoptic region of the anterior hypothalamus is still recognized as the major thermoregulatory center in the central nervous system (CNS)[3]. Pulse rate and respiratory rate are considered critical vital signs to determine the physical status i.e. well-being of the children. This has been contemplated as the initial measurement in children presenting with fever or other illnesses. These vital signs might have provided the children with the right life-saving interventions. Early warning signs are routinely used in health care centers and hospitals to assess the health deterioration in hospitalized children. The pulse and respiratory rates have increased with pyrexia in

children[4]. There are various interventions have emerged to reduce the heat generation in human. This can be possible either by physical methods or pharmacological methods. Physical method includes tepid sponging, fanning, bathing and cooling blankets which is frequently used to reduce the body temperature. Pharmacological based methods involving the administration of drug therapies. Paracetamol, ibuprofen and other drugs are routinely administered to subside the fever in human. The tepid sponging increases the heat loss by the process of conduction, convection and evaporation. The antipyretics (drugs) have exerted its function by suppressing the prostaglandin synthesis. Thus, promotes the vasodilation of the peripheral signals with increased heat loss by resetting the thermoregulatory center of the hypothalamus to normal[5]. Based on this background, the study was aimed to assess the efficacy of tepid sponging plus antipyretic medication vs antipyretic medication alone in management of fever among children.

MATERIALS AND METHODS

Study design

A Randomized Controlled Trail (A Non-Blinded Study) was performed in children admitted in hospital. The randomized control studies have described protocols that should meet the medical/scientific backgrounds, study design, benefit, risk assessment, overall plan of the study and analysis to be carried out. Clinical Trail Register Number: CTRI/2022/04/041652.

Study area

The study was conducted at Paediatric OPD and ward, Department of Paediatrics, Shri Sathya Sai Medical College and Research Institute, Thiruporur, Chengalpattu District, Tamil Nadu, India.

Study duration

The Randomized Control Trail to determine the efficacy and safety of the treatment to subside the fever in children was conducted for the period of 18 months from February 2021 to August 2022.

Study population

The study population is referred as the entire aggregation of cases that meet the designed criterion. The study subjects were the children with the age group of 6 months – 12 years who presented with fever, i.e the body temperature is >100.4^{o}F. Since the immune system is in the

developing stage, infants and children are more prone to various diseases and illnesses. Hence, the children from 6 months to 12 years were selected for the study. A total of 100 children with fever were taken for this study.

Study groups

The children were randomized into two groups of 50 each using Graph pad instant 3 software to analyse the efficacy of the treatment and the treatment groups as follows:

Group A= Tepid sponging + Antipyretic (oral paracetamol).

Group B= Antipyretic (oral paracetamol) alone.

Sample size

The sample size of this study was 100 children with pyrexia. Further, the children were bifurcated into two major groups containing 50 children in each group. The Group A was provided with the tepid sponging along with the antipyretic drug (oral paracetamol) and the Group B was administered with antipyretic (oral paracetamol) alone to know the efficacy of both the treatments.

Study procedures

Group A received the tepid sponging along with antipyretics and the Group B is administered with paracetamol alone. Digital thermometer was used to record the temperature and the initial recorded temperature was considered as zero minutes. Axillary temperature was monitored every 30 minutes subsequently for a period of two hours. The child's body temperature and vitals was assessed after thorough hand washing. To guarantee the patient's safety and privacy, a huge Mac sheet was put beneath him or her. The clothing was taken off after ensuring the child's privacy, and a sheet was placed over the child. Without touching the eyes, the face and neck were dabbed with a sponge. At the edge of the used basin, the first sponge was kept. A second sponge was used to dab the arms, beginning at the acromion and moving laterally until the fingers, then in the direction of the axilla, leaving the dabbed sponge in the axillary area. The other arm had the exact same procedure. Sponge was applied to the legs from the crotch to the feet. First sponge kept at basin's edge was used to dab the back and abdomen. The children in Group A were also received antipyretic (oral paracetamol) at dose of 15mg/kg/dose at 0 minute and temperature and vitals was monitored as

same interval as above. For Group B, the children were administered with the antipyretic drug alone. Fever grading and vitals were also measured in the mentioned intervals.

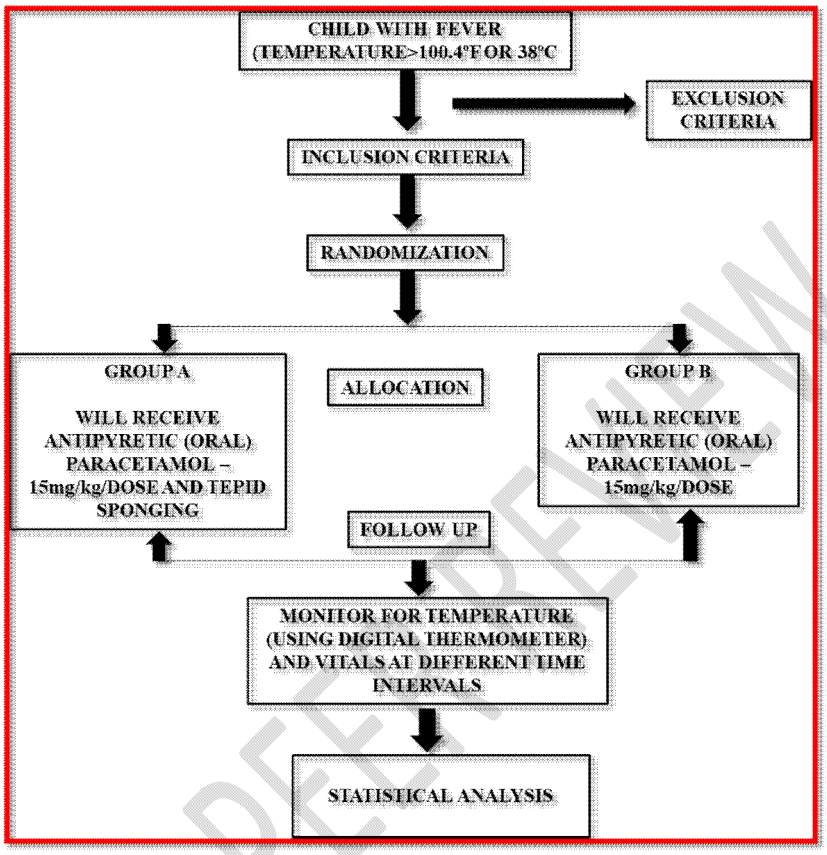

Figure 1: METHODOLOGY

Statistical analysis

The SPSS software was used to import all of the data entered into the Microsoft Excel sheet. SPSS, Version 23, was used for all of the analysis. To compare proportion, the chi square or fisher's exact test was employed. A p value of 0.05 was regarded as statistically significant when using the Unpaired t test to compare means between the two groups and the ANOVA to compare means before and after the intervention.

RESULTS

Totally 100 children with a diagnostic history of fever presented in the hospital, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpattu was selected for the study. Totally 100 children were randomized into two main groups, Group A and Group B and each group consisting of 50 children. The group A, children with pyrexia were provided with antipyretic medication and tepid sponging in order to reduce the body temperature gradually. Similarly, the Group B children are received the antipyretic medication alone. Children received treatments according to the group they belonged.

The female children between the age of six months to one year and six years to 12 years were prone to fever compared to male children in the same age group. The age between one year to five years and six to 12 years male children are easily affected by various infections, presenting with fever (Figure 2). The fever was noted in maximum number in each group (Group A and Group B) with the age of 1-5 years. No significant changes between the selected groups allowing to compare the group for other criteria (Figure 3). Totally 40 females and 60 males were taken for this randomized trail study. Nearly, equal number of male and female was distributed to each group which affirms the significance of this study (Figure 4). UTI is more predominant cause of fever in children under one-year of age, followed by bronchiolitis, pneumonia and ASOM. In children between age 1 to 5 years old, Pneumonia is act as the primary source for presenting fever. Bronchiolitis, viral fever contributes to certain extent. Acute tonsillitis is the major cause of raising the body temperature in children aged above 6 to 12. Subsequently, UTI, viral fever, enteric fever, scrub typhus might be the reason for fever in children. On the whole, UTI is presenting a severe cause for the children to show elevated body temperature (Figure 5).

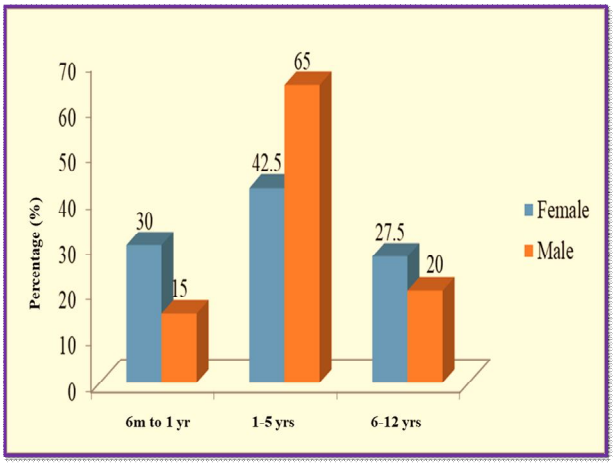

Figure 2: Age distribution vs gender in selected children

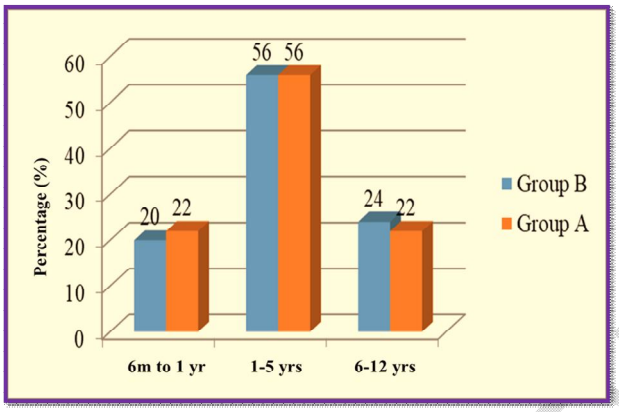

Figure 3: Age distribution vs group in selected children

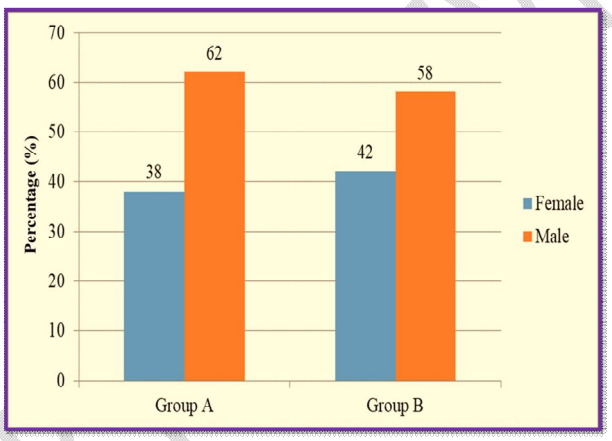

Figure 4: Gender distribution in the selected children

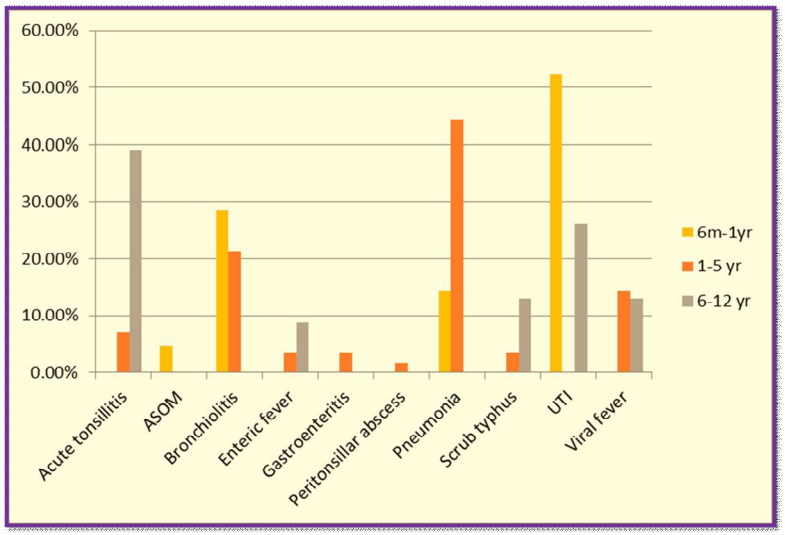

Figure 5: Causes of fever in the selected children

ANTHROPOMETRIC MEASUREMENT

There are no significant changes observed in children who were in same age under each group. In both the groups, the children under 12 months are in the mean height of 69 cm and mean weight of 7.5 kg. 1-5 years old children were 99 cm in mean height and 13 kg in mean weight were observed. The children between the age group of 6-12 years were found to have a mean height of 139 cm and mean weight of 29 kg in both groups. This results have significant correlation between two groups for conducting the experiments with selected treatments (Table 1).

Table 1: Anthropometric measurement

Anthropometry	Group A (mean+/-s.d)	Group B (mean+/-s.d)	p value
Height/length in cm			
Age < 1year	68.3+/-8.3	69.3+/-7.33	0.636
1-5 years	99.67+/-7.23	98.92+/-6.20	0.533
>5 years	138.23+/-10.22	139.33+/-11.77	0.520
Weight in kg			
Age < 1year	7.33+/-1.33	7.53+/-2.01	0.383
1-5 years	13.78+/-5.33	12.99+/-6.93	0.289
>5 years	28.8 +/-8.93	29.3+/-10.33	0.535

Values are represented as mean±SD of triplicates

TEMPERATURE VARIATIONS UPON TREATMENTS

The mean value of the temperature of the children in Group A was 102.4ºF and the Group B was 102.5ºF. There is no significant difference in temperature of the children in each group during the time of admission. This affirms that the treatment was appropriate to administered for the children in both the groups. there were no changes in the temperature observed after 30 minutes of treatment

given. No baseline changes in the body temperature were observed which remains at 102ºF. After 60 minutes of intervention, the temperature falls to 100.8ºF in group treated with tepid sponging along with antipyretic drug (Group A). Temperature in the children under Group B was noted with 101.5ºF. The results emphasized that, Group A has significant reduction in Temperature at 1 hour compared to Group B. In 90 minutes of treatment, the temperature was gradually decreased to 100ºF in Group A and 100.4ºF in Group B. The Group A and Group B was found to show the similar kind of efficacy on the reduction of body temperature among children. The final record was taken after 2 hours of treatment given to the children. The results shown that the temperature of Group A children was 98.9ºF and Group B children was 99.4ºF. This clearly depicted that the tepid sponging has a minute additive effect on subsiding the fever when administered along with antipyretics. This results supported that, tepid sponging with antipyretics and antipyretics alone showed indistinguishable potential on subsiding fever in selected group of children under respective groups (Figure 6).

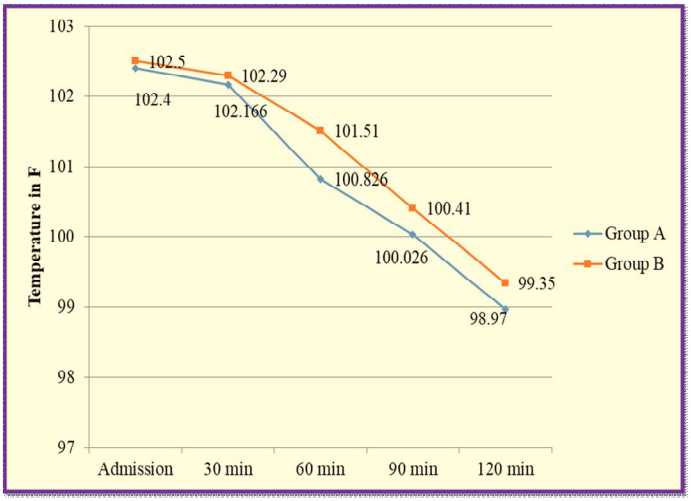

Figure 6: Temperature variations in the treated Group A and Group B children at certain intervals

FEVER GRADE COMPARISON

At end of the treatment day, 40 children from Group A and 41 children from Group B was completely recovered from fever. Nearly, 16 children were affected with mild fever in Group A, and at end of the treatment, 10 children cured. Whereas in Group B, 16 children recovered from mild fever. The children presenting severe fever in both groups were fully cured. Children affected with moderate

fever, almost 27 children from Group A and 23 children from Group B were entirely recovered. The fever grade comparison in the study between two groups at admission and 2 hours of post intervention showed that there were no significant changes noted. Eventually, the temperature grades were gradually decreased in both treatment groups (Table 2).

Table 2: Distribution as per grades of fever at admission and 2 hours post intervention

Fever grade in F at admission	**Group A n/%**	**Group B n/%**	**p value**
No <100.4	0	0	0.670
Mild (100.5-102.2)	16/32	20/40	
Moderate(102.2-104)	31/62	28/56	
High(104.1-106)	3/6	2/4	
Hyperpyrexia(>106)	0	0	
Fever grade in F at 2 hours	**Group A n/%**	**Group B n/%**	**p value**
No <100.4	40/80	41/82	0.370
Mild (100.5-102.2)	6/12	4/8	
Moderate(102.2-104)	4/8	5/10	
Severe(104.1-106)	0	0	
Hyperpyrexia(>106)	0	0	

Values are represented as mean±SD of triplicates.

VITAL MEASUREMENT (PULSE RATE AND RESPIRATORY RATE)

The children under age group of one year showed the pulse rate at the time of admission was 140 beats/minute and 138 beats/minute, in Group A and Group B respectively. And the value was drastically reduced to near the normal after 90 minutes of post interventions (111 beats/minute- Group A; 113 beats/minute- Group B). The pulse rate in the children who were under the age group of 6 to

12 years after one hour of treatment came to 100 beats/minute in Group A and 98 beats/minute in Group B. Conclusively, the pulse rate was correlated with the well-being of the children (Table 3). The gradual decrease in respiratory rate in children compared with the time of admission to the post two hours interventions. Children were slowly coming to normal stage as the pyrexia subsides. After, two hours of post interventions in both groups, almost attains the normal range of respiratory rate in children with pyrexia (0-12 months, 1-5 years and 6-12 years) (Table 4).

Table 3: Age wise comparison of pulse rate trends

Pulse rate (beats/min)comparison	Group A	Group B	P Value
< 1yr			
At presentation	140.2+/-3.3	138.99+/-4.2	
At 30 min	131+/-2.3	129.3+/-2.5	<0.001
At 60 min	121.5+/-7.1	118.3+/-3.2	
At 90 min	111.3+/-5.3	113.4+/-2.3	
At 120 min	112.5+/-3.5	114.3+/-6.6	
1-5 years			
At presentation	130.44+/-4.3	129.6+/-3.2	<0.001
At 30 min	120.45+/-3.6	121.33+/-5.3	
At 60 min	112.33+/-3.2	113.7+/-2.1	
At 90 min	100.6+/-3.7	101.5+/-3.5	
At 120 min	100.3+/-5.3	102.3+/4.4	
6-12 years			
At presentation	120.66+/-2.3	121.3+/-6.3	<0.001
At 30 min	110.3+/-5.3	112.33+/-6.9	
At 60 min	100.1+/-4.3	98.3+/-5.3	
At 90 min	92.4+/-4.6	94.5+/-5.6	

At 120 min	90.3+/-5.5	92.3+/-5.4	

Values are represented as mean±SD of triplicates

Table 4: Age wise comparison of Respiratory rate trends

Respiratory rate (breaths/min)comparison	Group A	Group B	P Value
< 1year			
At presentation	50.3+/-4.2	49.3+/-4.7	
At 30 min	42.3+/-2.3	40.6+/-2.33	<0.001
At 60 min	35.3+/-2.3	34.5+/-2.3	
At 90 min	30.2+/-2.3	30.3+/-3.5	
At 120 min	28.2+/-2.3	29.3+/-3.5	
1-5 years			
At presentation	41.3+/-2.3	40.66+/-2.44	<0.001
At 30 min	32.3+/-2.2	33.3+/-4.3	
At 60 min	30.2+/-2.3	28.3+/-2.2	
At 90 min	24.3+/-3.5	23.6+/-4.6	
At 120 min	24.3+/-3.5	23.5+/-4.4	
6-12 years			
At presentation	30.3+/-5.3	32.33+/-2.7	<0.001
At 30 min	24.33+/-4.3	24.3+/-2.5	
At 60 min	20.3+/-3.3	18.2+/-2.3	
At 90 min	15.6+/-2.5	14.9+/-3.98	
At 120 min	15.1+/-2.3	14.6+/-3.2	

Values are represented as mean±SD of triplicates

DISCUSSION

The study was aimed to evaluate the potential use of tepid sponging with antipyretic medication and antipyretic medication alone in the management of fever among children and also to find the most common cause of fever among the study population. The distribution of age versus gender in our study exhibited that, the female children between the age of six months to one year and six years to twelve years were prone to fever compared to male children in the same age group. The age between one year to five years and six years to twelve years male children are easily affected by various infections, presenting with fever. Comparatively, the results of the distribution of age versus group were interpreted as no significant changes observed in each group with different aged children. The fever was noted in maximum number in each group (Group A and Group B) with the age of 1-5 years. Totally, 40 females and 60 males were taken for this randomized trail study. Nearly, equal number of male and female was distributed to each group which affirms the significance of this study. UTI is contemplated as the predominant cause of fever in children under one-year of age, followed by bronchiolitis, pneumonia and ASOM. Shreds of scientific evidences also supported our study. A study conducted at Taiwan Medical Centre, 126 children were selected for the study to analyse the causes of fever[6]. Another study by Guillebaud *et al*., showed that, among 682 febrile children, viral infections was found to be the prior causes for fever followed by malaria and bacterial infections[7].

The children between the age group of 6-12 years were found to have a mean height of 139 cm and mean weight of 29 kg in both groups. This results have significant correlation between two groups for conducting the experiments with selected treatments. No baseline changes in the mean body temperature were observed which remains at 102°F. After 60 minutes of intervention, the mean temperature falls to 100.8°F in Group A. The mean temperature in the children under Group B was noted with 101.5°F. The results emphasized that, tepid sponging with antipyretic medication (Group A) has significant reduction in Temperature at 1 hour compared to antipyretic medication alone group (Group B). Various pieces of scientific evidences consistent with our findings. The use of antipyretics is opposed due to potential negative side effects, the usefulness of fever as a diagnostic indicator, and the potential role of fever in supporting the body's defense mechanisms. Both caregivers at home and nurses in hospitals frequently use cold water sponging to reduce fever. However, there is debate over its efficacy in lowering fever. Some authors contend that it is harmful, uncomfortable for kids, and should be abandoned[8]. A study conducted in Nigeria on utilizing sponging in cold water for the first 30 minutes was found to be fairly effective at bringing down body temperature. The infants were still

febrile (temperature of 38.45°C) despite statistically significant temperature declines from mean baseline temperature at 60, 90, and 120 minutes (P = 0.000, 0.003, and 0.019, respectively). Similar findings were seen in the paracetamol group, which saw a steady, continuous reduction in body temperature, reaching 37.12°C after 120 minutes. The proportion of afebrile kids in the two groups also followed a similar pattern[9]. The Sponging Study Group, situated in the United States of America, conducted a study that came to the conclusion that sponging had little to no effect on fever decrease after 30 minutes[10].

CONCLUSION

Fever is the most common symptoms for almost many diseases and illnesses in human. The body temperature increases with various environmental, physiological and biological stimuli. Ancient to modern, various physical and pharmacological methods have become materialized to reduce the body temperature, especially in children. From the results of our current study, it is concluded that, although the need for antipyretic medicines is debatable, it is recommended that, in situations when they are prescribed, antipyretic medications be the first line of treatment. Physical methods can also be administered by parents or caregivers alone or along with antipyretic medications to subside the pyrexia among children who don't experience any discomfort during the procedure until they reach the health care facility for definitive treatment of underlying cause of fever and the procedure can also be continued in healthcare facility by the paramedics until body temperature normalize to baseline.

CONSENT

The parents whose children were selected for this randomized controlled study were explained in detail about the procedure and the objectives of the study in their native language.The study was conducted after obtaining informed written consent.

ETHICAL APPROVAL

The study was conducted after getting the approval from the Institutional ethical committee.

REFERENCES

1. Akyirem S, Bossman IF. Is tepid sponging more effective than paracetamol at relieving fever in febrile children in hot tropical climates? a mini review. Ghana Medical Journal. 2021;55(1):60-8.

2. Wright WF, Auwaerter PG. Fever and fever of unknown origin: review, recent advances, and lingering dogma. InOpen Forum Infectious Diseases 2020 May (Vol. 7, No. 5, p. ofaa132). US: Oxford University Press.

3. Jose J, Jose JP, Baby G. Effect of tepid sponging versus warm sponging on body temperature and comfort among under-five children with pyrexia. Indian journal of pediatrics. 2022;89(5):516.

4. Fleming S, Thompson M, Stevens R, Heneghan C, Plüddemann A, Maconochie I, Tarassenko L, Mant D. Normal ranges of heart rate and respiratory rate in children from birth to 18 years of age: a systematic review of observational studies. The Lancet. 2011 Mar 19;377(9770):1011-8.

5. Walter EJ, Hanna-Jumma S, Carraretto M, Forni L. The pathophysiological basis and consequences of fever. Critical Care. 2016;20(1):1-0.

6. Kuo N, Su NY, Hou SK, Kang YN. Effects of acetaminophen and ibuprofen monotherapy in febrile children: a meta-analysis of randomized controlled trials. Arch Med Sci. 2021 Aug 22;18(4):965-981.

7. Guillebaud J, Bernardson B, Randriambolamanantsoa TH, Randrianasolo L, Randriamampionona JL, Marino CA, Rasolofo V, Randrianarivelojosia M, Vigan-Womas I, Stivaktas V, Venter M. Study on causes of fever in primary healthcare center uncovers pathogens of public health concern in Madagascar. PLoS neglected tropical diseases. 2018 Jul 16;12(7):e0006642.

8. 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 Family Med Prim Care. 2013 Apr;2(2):153-8. doi: 10.4103/2249-4863.117409. PMID: 24479070; PMCID: PMC3894045.

9. Agbolosu NB, Cuevas LE, Milligan P, Broadhead RL, Brewster D, Graham SM. Efficacy of tepid sponging versus paracetamol in reducing temperature in febrile children. *Ann Trop Paediatr.* 1997;17:283–8.

10. Basavaraj, C. K., Pocha, S. G., & Dhati, R. M. (2018). Effectiveness of Antipyretic with Tepid Sponging Versus Antipyretic Alone in Febrile Children: A Randomized Controlled Trial. *Journal of Nepal Paediatric Society*, *37*(2), 129–133.