

Research article

Effect of recorded maternal voice on procedure pain- a double blinded randomized controlled trial

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Abstract

This double-blinded randomized controlled trial included 46 children between 4 to 12 years of age with haematological malignancy, scheduled for bone marrow examination at tertiary care hospital of India. Subjects were enrolled into two groups (23 each) by stratified random sampling based on the type of procedure scheduled to them. The maternal voice was recorded for 3 minutes before the procedure and headphones was placed during the procedure, for all children but maternal voice was played only to intervention group by another person to blind the researcher. Child's cooperation for the entire procedure was recorded as video by researcher and later video was rated using FLACC behavioural scale. Pain perception was rated by children using Wong-Baker faces pain rating scale. The results showed a significant difference in the level of child's cooperation with mean (SD) distress score of 7(2) in control group and 4.52(2.15) in the intervention group ($p=0.0002$). There was no significant difference in pain perception of control and intervention groups. Significant moderate positive correlation (0.31) was found in the child's distress and pain perception levels ($p=0.03$). There was significant negative association of age was found with the child's distress (-0.30) and pain perception level (-0.33) at ($p=0.04$, 0.02) respectively. In conclusion, recorded maternal voice can significantly decrease the child's distress level thus improve the child's cooperation during bone marrow examination along with local anaesthesia. As the child's cooperation increased, the child perceived less pain during the procedure. Older children were more cooperative and perceived less pain as compared to younger ones. Nurses are at an ideal position to implement this cost-effective, non-pharmacological intervention for children undergoing bone marrow examination.

INTRODUCTION

Cancer in children is less common as compared to adults. In children, cancers usually occur suddenly, without early symptoms, and have a high rate of cure. Irrespective of the type of cancer, pain is

one among the most frequently reported symptoms. Cancer pain is a complex pain and various mechanisms are responsible for it. When cancer is diagnosed at early stages, then children usually experience pain due to diagnostic and therapeutic procedures. However, at the advanced stage the pain is

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usually due to the progression of cancer itself (Afshan, G., & Bashir, K. 2014).

Paediatric oncology patients have reported pain as a greater problem from diagnostic and treatment procedure than pain from the malignant disease itself.

As per the 2018 world demographic profile, children (0-14 years) account 25.4% which is around 1.95 billion of total world population. Based on international association of cancer registry (IACR) paediatrics dataset of last decade, approximately 11.4% of the total cases, comes under age group of 0-14 years, out of which 1.7% covered by south Asia (India). In children (0-14 years), the leading cancers in all regions are leukaemia, lymphoma and CNS tumours. The incidence of cancer increased from 124 to 140 per million per years over the last decade (Steliarova-Foucher E, et al.2001). As per the Indian cancer registries, out of total childhood (0-14) cancers, around 40-50% are leukaemia and 15-20 % are lymphoma (Asthana, et al. 2018).

To diagnose and follow up the hematological disorders, bone marrow examination is considered an essential tool (Degen C., et al 2010). Bone marrow examination consists of bone marrow aspiration (BMA) and bone marrow biopsy (BMB) which are invasive procedures. Many times, only bone marrow aspiration is needed like in leukemia, but in lymphoma both the procedures are preferred. Deep, dull, and aching pain felt when liquid portion of bone marrow is withdrawn by syringe whereas severe pain and pressure felt when biopsy needle inserted in the bone. Both bone marrow aspiration and biopsy are associated with morbidity, discomfort and pain.

Anxiety, fear and pain related to procedure are more in children. The pain and anxiety manifests as distress or lack of cooperation by the child which hinder, the success and

timely completion of the procedure (Degen, C., et al 2010).

Anxiety, fear and pain related to procedure are affected by other variables such as frequency of the procedure performed, procedure type. Anxiety and distress subsequently can affect the clinical parameters such as blood pressure and heart rate (Yuval Karacan Y,2017). Despite being performed for many years, using different protocols, the procedure still remains painful for patients (Hjortholm N, et al. 2013). Invasive procedures have been reported as the most difficult part of cancer treatment, leading to post traumatic stress symptoms in long term survivors (Ghasemi A, et al. 2013.)

General anesthesia or combination of analgesia and sedative drugs are recommended during painful procedures in pediatric oncology by The World Health Organization and the American Academy of Pediatrics (AAP) (Zeltzer LK, et al.1990) but general anesthesia require additional time such as preparation time before the procedure, recovery time afterward and require additional trained personnel such as anesthesiologist. All these factors increase the cost of the procedure and make the institute less likely to use sedation and general anesthesia if they can avoid it. Along with all these issues sedation and general anesthesia carry small risk of post procedural adverse reactions and complications like vomiting, agitation and headache.

Due to less actual time for bone marrow aspiration and biopsy procedure, Infiltration of Local anaesthesia used as the main form of analgesia in most of the health care settings. As the children are awake, they demand to be accompanied with parents inside the procedural room but parental presence is not possible in every setting. Separation from parents creates considerable distress, leads to un-cooperativeness during the entire procedure.

Non pharmacological factors play an important role in influencing pain and distress level during the invasive procedures (Zahid MF, 2005). Recorded Maternal voice can be the effective non-pharmacological intervention to control child's distress and make them cooperative during the procedure, which is less costly and can be administered by nurses (Gupta HV, et al. 2014).

Study aimed to assess the effectiveness of recorded maternal voice on the child's cooperation and pain perception during bone marrow examination.

METHODS

This study has a quantitative approach through double blinded randomized controlled group design.

Recruitment and Setting

Participants were recruited through stratified random sampling. Children scheduled for bone marrow examination were assessed for eligibility based on inclusion and exclusion criteria in the medical oncology OPD, As shown in table 1. Patients were divided into two strata, bone marrow aspiration and biopsy on the basis of procedure type scheduled to them. The basis for dividing into strata was the pain level during the procedure. Bone marrow biopsy is more painful procedure than aspiration. If patient was scheduled for both the procedures then they were kept in biopsy strata. Separate random tables were generated for both the strata. Just before the procedure patient's group allocation was communicated to third person who administers the intervention to the patients. Recorded maternal voice was played to only intervention group of children but the headphones were kept for all the children by the third person to blind the researcher and the other patients. The allocation and randomization are shown in figure 1.

Bone marrow examination is mostly an OPD procedure for cancer patients who are taking treatment under medical oncology department. It is conducted in procedure room of OPD, of Dr. B.R.A Institute-Rotary Cancer Hospital (IRCH), AIIMS. Procedure room resembles an operating room with two tables, one monitor and articles required for procedure. Out of two, one table which is towards the monitor is preferred for pediatric cases. All the procedures are performed from Monday to Friday every week. Chairs are placed outside the room where patient and relatives can wait. A side room is available near the room and it was utilized for recording.

Table 1
Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
1. Accompanied with mother	1. Children with significant hearing deficits.
2. Mother is able to speak and understand HINDI/ENGLISH	2. Children diagnosed with cognitive disability.
3. Willing to participate.	3. Children with critical illness.

Data collection

Data collection was done by using three different tools, out of which FLACC behavioural scale and Wong-Baker faces pain rating scale were standardized tools and socio-demographic with clinical profile was the structured tool. Socio-demographic profile consists of age, sex, birth order, education of mother, area of residence, family monthly income and child attend school. Clinical profile consists of diagnosis, procedure type, frequency of the procedure performed, heart rate, blood pressure and oxygen saturation.

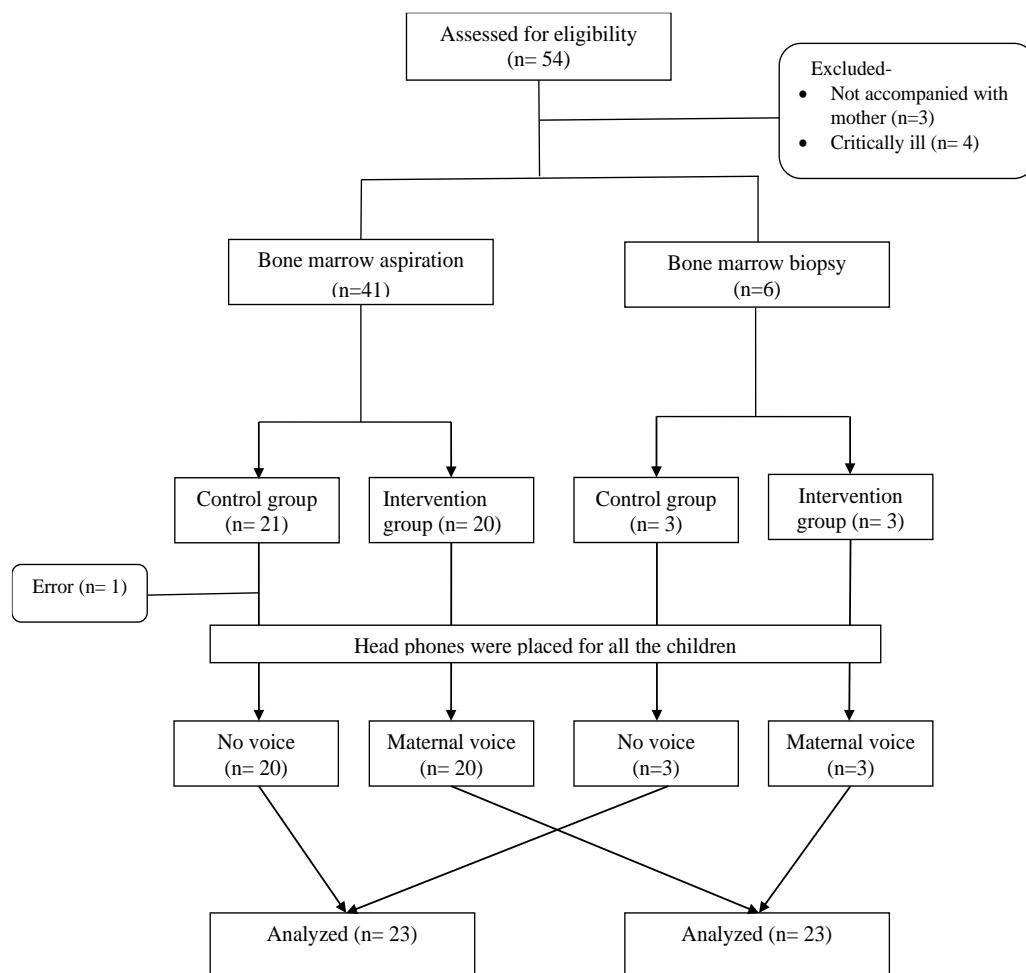


Figure 1
Consort Diagram

Other than tools devices like mobile phones and headphones were used to record and implement the intervention during the study.

1. Intervention

Recorded maternal voice was used as intervention for the study. For recording the maternal voice of respective child they were called to the side room to give instructions before recording, where content for the voice recording was explained to the mothers with the help of a downloaded procedural video. Time was given to think and once the mothers were ready, recorder was set with the instruction 'start'. Talk was recorded for 3 minutes, and after 3 minutes the voice recorder was turned off and mothers were instructed to 'stop'. The recorded voice was checked for clarity and content

and then saved to memory card with the serial number of the respective child.

2. Administration of the intervention:

Once the child laid down on the procedural table, the recorded maternal voice of their respective mother was played to the child of intervention group whereas headphone without any voice was placed to the child of control group for the entire procedure to blind the researcher.

3. Procedure for data collection:

Once the eligibility criteria assessed, socio-demographic data were collected and maternal voice was recorded for all the children by the researcher. Subjects were randomly allocated into control and interventional group with the help of computer-generated random table by

second person who was not in the contact with the patients. Recorded maternal voice were handed over to the third person who was administering the intervention. Once the child laid on procedural table, headphone was placed for all children by the third person and voice was played to interventional group while the control group was not heard any voice. Vitals were measured before and just after the procedure for all children. Child's cooperation for the entire procedure was recorded as video by the researcher and later on, video recording of the procedure was rated using FLACC behaviour scale. Whereas pain perception of the child was assessed after the procedure by asking subjectively to rate the scale.

Data analysis:

All recorded data were coded and scored into Microsoft Excel 2007 spread sheet. All the entries were checked for errors. STATA 14 version was used for statistical analysis. Descriptive and inferential statistics were used. Descriptive statistics used in the study were frequency, percentage, mean and median. For inferential statistics tests, two sample t test, Paired t test, Pearson chi square test, fisher exact test, Kruskal Wallis, Wilcoxon rank sum test and Pearson's correlation coefficient were used. Two sample t tests were used to compare the means of clinical variable, physiological variable, child cooperation and pain perception between the two groups. Chi square test and fisher exact test was used to compare the means of demographic variable between the two groups. Pearson correlation coefficient was used to correlate the child's cooperation and pain perception. Wilcoxon and Kruskal Wallis tests were used to compare the median of demographic and clinical variable with child cooperation and pain perception. For all the tests, p value<0.05 was considered as significance level.

RESULT

The final sample comprises 46 subjects where, the mean with Standard deviation age of children was 7.6 ± 2.88 years in the control group and 7.2 ± 3.11 in the intervention group. Majority of children in both the groups were male. About 34.8% of children in both the groups were the second child of the family. In the control group 34.8% mothers had education up to graduation and above and in the intervention group 43.5% mothers had education up to higher secondary. Majority of children were from the rural community. 60.9% in the control group and 39.1% in the intervention group of children family monthly income was ₹ 5,000-15,000. Other clinical and bio-physiological variable are shown in the table 2,3 and 4 below.

Socio-demographic variables	Control Group (n=23)	Intervention Group (n=23)	p value
Age (Mean \pm SD)	7.6 \pm 2.88	7.2 \pm 3.11	0.649 ^a
Frequency (%)			
Sex			
Male	17 (73.9)	13 (56.5)	0.216*
Female	6 (26.1)	10 (43.5)	
Birth order			
First	7 (30.4)	11 (47.8)	0.511 [#]
Second	8 (34.8)	8 (34.8)	
Third	5 (21.8)	2 (08.7)	
More than third	3 (13.0)	2 (08.7)	
Mother's education			
Graduation and above	8 (34.8)	5 (21.7)	0.361 [#]
Higher secondary	6 (26.1)	10 (43.5)	
Primary school	5 (21.7)	2 (08.7)	
Illiterate	4 (17.4)	6 (26.1)	
Area of residence			
Rural	7 (30.4)	10 (43.5)	0.359*
Urban	16 (69.6)	13 (56.5)	
Family monthly income			
Above 15,000	8 (34.8)	10 (43.5)	0.232 [#]
5,000-15,000	14 (60.9)	9 (39.1)	
Below 5,000	1 (4.3)	4 (17.4)	

^aTwo sample t test, *Chi square test, [#]Fisher exact test, (p<0.05)

Table 3
Clinical variables of children in control and intervention group (n=46)

Clinical Variables	Control Group (n=23)	Intervention Group (n=23)	p value*
Frequency (%)			
Diagnosis			
ALL	16 (69.6)	11 (47.8)	0.435
AML	3 (13)	7 (30.4)	
HL	2 (8.7)	2 (8.7)	
NHL	2 (8.7)	3 (13.1)	
Procedure type			
Bone marrow biopsy	3 (13.1)	3 (13.1)	1.000
Bone marrow aspiration	20 (86.9)	20 (86.9)	

*Fisher exact test, ($p < 0.05$)

ALL: acute lymphocytic leukemia, AML: acute myelocytic leukemia, HL: hodgkin lymphoma, NHL: non-hodgkin lymphoma

As shown in table 5, the mean distress (range) score of FLACC behaviour scale was higher, 7 ± 2 (3-10) in control group as compared to 4.52 ± 2.15 (0-8) in the interventional group. Decreased mean distress score indicates increased child

cooperation during the procedure. The mean score of Wong Baker FACES pain rating scale of children in the control group was slightly higher 7.04 ± 2.88 , as compared to 6.95 ± 2.94 in the intervention group but the p value was not significant (0.919) between both the groups.

As shown in table 5, the “r” value of Pearson’s correlation was 0.31, which indicates that there was moderate positive correlation between mean distress score of FLACC behaviour scale and mean score of Wong Baker faces pain rating scale of children. So, if child’s cooperation increases, pain perception decreases and vice-versa.

As shown in table 6, for continuous variables Pearson’s correlation was calculated. Correlation “r” value between age and child’s cooperation was -0.30 which indicate the weak negative correlation whereas Bio-physiological variables were not correlated significantly with child’s cooperation and pain perception.

Table 4
Bio physiological variables of children in control and intervention group (n=46)

Physiological variables	Control Group (n=23)	Intervention Group (n=23)	p value [#]
Mean \pm SD			
Heart rate			
Before the procedure	132 \pm 19.45	125.65 \pm 24.25	0.33
After the procedure	140 \pm 22.04	132.43 \pm 24.52	0.23
Blood pressure			
Before the procedure	(126.43 \pm 9.5)/(81.86 \pm 9.1)	(121.73 \pm 11.5)/(83 \pm 5.9)	0.13
After the procedure	(130.21 \pm 8)/(86.60 \pm 8.9)	(128.69 \pm 7.08/85.43 \pm 5.13)	0.49
Oxygen saturation			
Before the procedure	98.43 \pm 1.27	98.56 \pm 0.84	0.68
After the procedure	95.73 \pm 2.32	96.13 \pm 1.83	0.14

[#] Two sample t test, ($p < 0.05$)

Table 5
Child’s cooperation and Pain perception of the control and intervention group (n=46)

Indicators	Control Group (n=23)	Intervention Group (n=23)	p value* (mean difference)	r value	p value
Mean \pm SD (min-max)					
Child’s Cooperation	7 \pm 2 (3-10)	4.52 \pm 2.15 (0-8)	0.0002	0.31	0.03
Interpretation	Severe discomfort/pain	Moderate discomfort/ pain			
Pain Perception	7.04 \pm 2.88 (0-10)	6.95 \pm 2.94 (2-10)	0.919		
Interpretation	Hurts whole lot	Hurts even more			

* Two sample t test, ($p < 0.05$)

Table 6
Association of child's cooperation and pain perception with selected variables (n=46)

Variables	Child's cooperation (correlation 'r')	p value	Pain perception (correlation 'r')	p value
Age	-0.30	0.04	-0.33	0.02
Heart rate	0.16	0.28	0.06	0.68
Blood pressure	0.25	0.09	0.16	0.27
Oxygen saturation	0.05	0.71	0.02	0.88

r: Pearson's correlation coefficient, ($p < 0.05$)

DISCUSSION

Study findings confirm that recorded maternal voice improves the child's cooperation which is consistent with study done by (Rajan D et al. 2017), who found that distress score decreases due to maternal voice. The study by (Azarmnejad et al. 2015) showed the significant effect of mother's voice on reducing the pain. The study done by (G Chirico et al.) showed that using recorded maternal voice appeared safe and effective to limit pain in preterm infants, are also consistent with the present study findings. Study on the effect of non-pharmacological intervention to decrease child distress and improve cooperation such as audio-visual distracting technique used by (Bagnasco A. et al.) in a study which showed that audio-visual distraction effectively improved pain management and favoured child's cooperation during venepuncture.

Present study finding shows no effect of recorded maternal voice on pain perception which is consistent with the study done by (Vadlamudi Haarika et al. 2017) showed that recorded mother's voice is not effective in decreasing pain perception during venepuncture.

The present study finding shows a moderate positive correlation between child's cooperation and pain perception which is consistent with the systemic review done by (Oliveira et al.) which gather scientific evidence of distress associated pain in infants and children.

The finding of the present study that age is negatively correlation with pain is

consistent with the study done by (Yuvali Karacan Y et al. 2017) on patients with cancer which showed that pain and anxiety has a negative relationship with age.

Association of other demographic and clinical variables are not found significant with child's cooperation and pain perception.

The findings of the present study that recorded maternal voice did not make any difference in the physiological variable like heart rate, blood pressure and oxygen saturation is consistent with the study done by (Johnston CC et al. 2007) which showed that maternal voice did not have any impact on heart rate and oxygen saturation. another study done by (Johnston CC et al. 2012) also reported no significant difference on any of the physiological parameter of children by maternal touch and talk during invasive procedure.

The study done by (Gorfinkle KS et al. 1998) reported that even the clown therapy was effective in reducing child's distress but doctors found difficulty to perform the procedure with clown, but in the present study researcher has not come across any difficulty reported from doctors and nurses to perform the procedure while administering intervention.

CONCLUSION

The study concluded that recorded maternal voice can significantly increase the cooperation of children during the bone marrow examination along with local anaesthesia. As the cooperation of children increases, they perceived less pain during

the procedure. Older children were more cooperative and perceived less pain as compared to younger ones. Nurses are at best position to implement this cost effective, non-pharmacological intervention for children undergoing bone marrow examination. Nurses in other paediatric settings can use this strategy in situations where children are separated from their parents like pre-anaesthesia rooms.

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CONFLICT OF INTEREST

The research is free from conflict of interest.

REFERENCES

1. Afshan, G., & Bashir, K. (2014). Cancer pain in children: A two-step strategy. *Anaesthesia, Pain and Intensive Care*, 18, 106–110.
2. Steliarova-Foucher E, Colombet M, Ries LAG, et al. International incidence of childhood cancer, 2001-10: a population-based registry study [published correction appears in *Lancet Oncol*. 2017 Jun;18(6):e301]. *Lancet Oncol*. 2017;18(6):719-731. doi:10.1016/S1470-2045(17)30186
3. Asthana, S., Labani, S., Mehrana, S., & Bakhshi, S. (2018). Incidence of childhood leukemia and lymphoma in India. *Pediatric Hematology Oncology Journal*, 3(4), 115–120. <https://doi.org/10.1016/j.phoj.2017.12.004>
4. Degen, C., Christen, S., Rovo, A. et al. Bone marrow examination: a prospective survey on factors associated with pain. *Ann Hematol* 89, 619–624 (2010). <https://doi.org/10.1007/s00277-010-0934-0>
5. Yuvalı Karacan Y, Demircioğlu B, Ali R. Pain, anxiety, and depression during bone marrow aspiration and biopsy. *Agri*. 2017 Oct;29(4):167-172. doi: 10.5505/agri.2017.90582. PMID: 29171647.
6. Hjortholm N, Jaddini E, Hałaburda K, Snarski E. Strategies of pain reduction during the bone marrow biopsy. *Ann Hematol*. 2013 Jan;92(2):145-9. doi: 10.1007/s00277-012-1641-9. Epub 2012 Dec 6. PMID: 23224244; PMCID: PMC3542425.
7. Ghasemi A, Gharavi Fard M, Sabzevari A. General anesthesia for lumbar puncture and bone marrow aspiration /biopsy in children with cancer. *Iran J Ped Hematol Oncol*. 2013;3(2):54-8. Epub 2013 Apr 22. PMID: 24575270; PMCID: PMC3915451.
8. Zeltzer LK, Altman A, Cohen D, LeBaron S, Munuksela EL, Schechter NL. American Academy of Pediatrics Report of the Subcommittee on the Management of Pain Associated with Procedures in Children with Cancer. *Pediatrics*. 1990 Nov;86(5 Pt 2):826-31. PMID: 2216645.
9. Dunlop TJ, Deen C, Lind S, Voyle RJ, Prichard JG. Use of combined oral narcotic and benzodiazepine for control of pain associated with bone marrow examination. *South Med J*. 1999 May;92(5):477-80. doi: 10.1097/00007611-199905000-00005. PMID: 10342892.
10. Zahid MF. Methods of reducing pain during bone marrow biopsy: a narrative review. *Ann Palliat Med*. 2015 Oct;4(4):184-93. doi: 10.3978/j.issn.2224-5820.2015.09.02. PMID: 26541397.
11. Gupta HV, Gupta VV, Kaur A, Singla R, Chitkara N, Bajaj KV, Rawat HC. Comparison between the Analgesic Effect of two Techniques on the Level of Pain Perception During venipuncture in Children up to 7 Years of Age: A Quasi-Experimental Study. *J Clin Diagn Res*. 2014 Aug;8(8):PC01-4. doi: 10.7860/JCDR/2014/9731.4675. Epub 2014 Aug 20. PMID: 25302240; PMCID: PMC4190764.
12. Rajan D, Lakshmanan G, Gupta SK, Sivasubramanian R, Saxena A, Juneja R. Effect of Recorded Maternal Voice on Child's Cooperation During Cardiac Catheterization - A randomized controlled trial. *Indian Pediatr*. 2017 Mar 15;54(3):204–7.
13. Azarmnejad E, Sarhangi F, Javadi M, Rejeh N. The Effect of Mother's Voice on Arterial Blood Sampling Induced Pain in Neonates Hospitalized in Neonate Intensive Care Unit. *Glob J Health Sci*. 2015 Nov;7(6):198–204.

14. Randomised study showed that recorded maternal voices reduced pain in preterm infants undergoing heel lance procedures in a neonatal intensive care unit - Chirico - 2017 - Acta Paediatrica - Wiley Online Library [Internet]. [cited 2019 Jan 21]. Available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/apa.13944>
15. Bagnasco A, Pezzi E, Rosa F, Fornonil L, Sasso L. Distraction techniques in children during venipuncture: an Italian experience. *Journal of Preventive Medicine and Hygiene*. 2012 Mar;53(1):44-48. PMID: 22803319.
16. [Vadlamudi Haarika, Palanisamy Soundararajan, Sumathy Sundar , Rajaramalingam, Dhandapani Gunasekaran and Karuppiah Pandi. (2017); The Effectiveness Of Music And Mother\'S Voice On Pain Reduction During Venepuncture In Neonates- A Randomized Control Trial *Int. J. of Adv. Res.* 5 (Feb). 2575-2579] (ISSN 2320-5407). www.journalijar.com
17. Johnston CC, Filion F, Nuyt AM. Recorded maternal voice for preterm neonates undergoing heel lance. *Adv Neonatal Care Off J Natl Assoc Neonatal Nurses*. 2007 Oct;7(5):258-66.
18. Johnston CC, Rennick JE, Filion F, Campbell-Yeo M, Goulet C, Bell L, et al. Maternal Touch and Talk for Invasive Procedures in Infants and Toddlers in the Pediatric Intensive Care Unit. *J Pediatr Nurs*. 2012 Apr 1;27(2):144-53.
19. Gorfinkle KS, Slater JA, Bagiella E, Tager FA, Labinsky EB. Child Behavioral Distress During Invasive Oncologic Procedures and Cardiac Catheterization with the Big Apple Circus Clown Care Unit • 55. *Pediatr Res*. 1998 Apr 1;43(S4):12.