

The efficacy of non-pharmacological methods of pain management in school age children receiving venepuncture in a paediatric department: a randomized controlled trial of audiovisual distraction and routine psychological intervention

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Summary

Questions under study/principles: Non-pharmacologic analgesia has been demonstrated to alleviate pain and distress in invasive procedures. Nevertheless, the practice has not been adopted widely in paediatric departments because nurses are often too busy to perform a time consuming procedure.

Methods: Three hundred patients (8–9 years) requiring venepuncture for intravenous treatment were randomized into audiovisual distraction group (n = 100, watching cartoon films), intervention group (n = 100, receiving psychological intervention) and control group (n = 100, without any intervention).

Results: There was no significant difference ($P > 0.05$) between the audiovisual distraction and the intervention groups for cooperation, venepuncture times and pain intensity (assessed with visual analogue scale, VAS). However, cooperation in the control group was more passive than in the intervention group ($P < 0.05$) but not apparently different to the audiovisual distraction

group ($P > 0.05$). Venepuncture time was significantly higher in the control group than in the other two groups ($P < 0.05$). Venepuncture caused moderate pain in children (VAS score: 5.22 ± 2.53 in the control group). VAS scores indicated that procedures were more painful in the control group than in the audiovisual distraction or the intervention group (VAS score: 4.55 ± 2.26 and 4.38 ± 2.32 in the audiovisual distraction and intervention groups respectively, $P < 0.05$).

Conclusions: Audiovisual distraction was demonstrated to be effective in reducing self-reported pain, improving patient cooperation and increasing success rate in venepuncture procedures and was as successful as routine psychological intervention. It is highly recommended as an effective, labour saving and easy to administer analgesia and should be used to help prevent pain from venepuncture in school age children.

Key words: children; venepuncture; pain; audiovisual distraction; psychological intervention

Introduction

In a paediatric department many children undergo painful procedures such as venepuncture during treatment. Research suggests that prompt and accurate recognition and treatment of pain in children is important for their immediate comfort and lifelong development [1]. Despite the recent interest in paediatric pain assessment, prevention and treatment many children are still not adequately treated to alleviate pain [2, 3]. In addition,

the use of premedication analgesics and sedatives is unsuitable for minimally invasive procedures such as venepuncture, whereas it is obviously effective in improving pain control during invasive

Abbreviations

VAS visual analogue scale

CBSCV cooperative behaviour scale of children in venepuncture

procedures [4]. Non-pharmacologic intervention is considered a useful approach to improve infant and child experience of painful procedures [5–9]. It seems a safe, inexpensive and effective analgesia for short painful procedures [5–9]. In the literature, the role of several methods, such as hypnosis, distraction and guided imagery in alleviating pain has been well documented in paediatric patients undergoing frequent invasive medical procedures [10–12]. Of these, distraction is the most commonly used method for procedural pain of short duration [9, 13]. A growing number of studies looking at infants and children undergoing painful procedures suggest that this analgesic effect may indeed extend past the infant period into

childhood [1, 3, 5–9, 12]. Nevertheless, there are few studies performed to compare the efficacy of audiovisual distraction with routine psychological intervention in school age children receiving venepuncture. We hypothesized that the audiovisual distraction technique, a labour saving and easy to administer therapy, would reduce the child's pain during venepuncture procedure as effectively as other routine psychological interventions. This study compared the effect of audiovisual distraction with routine psychological intervention (ie explaining, therapeutic touch, encouragement and guided imagery) for school age children receiving venepuncture in a paediatric department.

Methods

Setting

This study was conducted in the paediatric department of Qingdao Municipal Hospital (Affiliated Municipal Hospital of Medical College, Qingdao University), a general Hospital of 2000 beds, serving a population of 7.2 million in Qingdao city, Shandong province (China).

Protocol

The protocol was approved by the institutional ethics review board at Qingdao Municipal Hospital and all subjects and their parents provided verbal consent for participation in the study.

Subjects

Children between 8 and 9 years of age requiring initial venepuncture for a period of intravenous treatment in the paediatric department were considered for inclusion in the study. Patient exclusion criteria were as follows: history of puncture during the past three months; treatment with anxiolytic or narcotic analgesics medication 72 h prior to the venepuncture; presence of insufficient mental development, alteration of mental status and cognitive impairment; or visual and auditory deficits.

Randomization

The consecutive eligible subjects were randomly assigned to an audiovisual distraction, intervention or control group according to random numbers from 1 to 300, generated by Research Randomizer (<http://www.randomizer.org/form.htm>). Patient group assignment was not known to research nurses until the time of patient enrolment by referring to consecutive sealed envelopes maintained in a designated location in the paediatric depart-

ment. After group allocation, patients' baseline characteristics, including demographic information (age and gender) and diagnosis, were collected from the medical records.

Intervention

All of the children, regardless of group assignment, were evaluated and treated according to the standard protocol. Patients in the audiovisual distraction group were given a choice of ten appropriate cartoon videos. A TV set coupled with a DVD player was provided for patients to play their favourite animated cartoons. During the showing of the cartoon films (about three minutes after the film began), venepuncture was performed by a registered nurse. Patients assigned to the intervention group received conventional psychological interventions in a fixed scheme (tab. 1) with no audiovisual distraction. The intervention methods, including explaining before venepuncture, therapeutic touch, encouragement and guided imagery during the procedure, were actualized by utilizing developmentally appropriate words and in a non-threatening manner. Patients in the control group underwent venepuncture without any special intervention, that is without audiovisual distraction or any of the other psychological interventions performed in the test groups. After venepuncture, patients and their parents were asked to complete standardized study instruments to assess pain intensity.

To minimize the bias, the vein for penetrating was localized on the dorsal venous rete of the hand. Venepuncture procedure was performed by two registered nurses with 17–25 years professional experience. If initial venepuncture was unsuccessful, a second attempt

Table 1

Psychological intervention scheme in the intervention group.

The following steps are performed by research nurses in the intervention group.

Before venepuncture

1. Provide for their comfort and gain the patient's cooperation.
2. Explaining to the patient: Why the patient requires intravenous treatment. Pain is unavoidable during the procedure, but if he/she cooperates with the nurse the experience would be shorter and less painful.

During the procedure

3. Therapeutic touch: Touch and massage the patient's hand and forearm to calm him/her before the needle prick.
4. Guided imagery: Ask and guide the child to imagine doing his/her favourite activity, eg eat an ice-cream and think about the sensations.
5. Encouragement: Inspire the child with courage and hope, eg ask the child to learn from another (adult or child with better cooperation) or tell him/her that the procedure would succeed soon, and praise him/her during and after the venepuncture.

Table 2

Cooperative behaviour scale of children in venepuncture (CBSCV).

Grade	Behaviour
0	Holds out the hand on his/her own initiative and cooperates with the nurse in procedure
1	Holds out the hand and has no crying during the procedure
2	Refuses to cooperate with the nurse and cries

only took place after a full five minute interval. Psychological intervention was practised by the same nurses who performed venepuncture and all of the nurses had received special training prior to this study.

Outcome measures

The observational visual analogue scale (VAS) was used for quantitative assessment of pain during the procedure. The horizontal VAS consists of a 10 cm horizontal line with two end anchors defining a scale ranging from 0 (no pain) to 10 (most pain). In this study, two end of the horizontal VAS were marked with a smiling face (no pain) and a crying face (most pain). Patients were asked to rate their pain distress on horizontal VAS after venepuncture.

To evaluate the cooperation of children in the three groups, we assessed the cooperative behaviour as a secondary outcome measure. A cooperative behaviour scale of children in venepuncture (CBSCV) was created to represent the cooperation of patients in this study. The CBSCV tool assesses child cooperation using behaviour during venepuncture procedure, rating on a scale of 0–2 (tab. 2). Prior to the study, several research nurses were trained by the research nurse coordinator in assigning CBSCV grades and other details related to outcome assessment.

As unsuccessful venepuncture prolongs the painful experience and it could impact with some other factors, such as child cooperation with the nurse, we defined the times of venepuncture in each child as further secondary outcome measure.

Data collection

The study was conducted from January 2005 to December 2006. Data collection efforts for all outstanding data forms ceased six weeks after the last required patient file was completed. Baseline characteristics, such as sex, gender, education status and indication for procedure were recorded. VAS score and CBSCV grade were assessed by the research nurses. Times for venepuncture were noted once the procedure was completed. All data were recorded and entered into SPSS for analysis.

Sample size

Based on previous measurements of pain on the Oucher scale (a 100 point scale), we estimated that the standard deviation of pain scores on the VAS scale (a 10 point scale) to be approximately 2.46. Assuming an alpha level of 0.05 and a power of 90%, we required a total sample size of 198 children to be able to detect a 1.41 point average VAS scale difference between two groups. Sample size was calculated using PPMS version 1.0 (Qingdao University, Medical College, China). In order to avoid baseline imbalances, total sample size was enlarged to 300 children.

Statistical analysis

Measurement data were expressed as the mean, standard deviation (SD) and range and enumeration data were expressed as proportions. Differences for baseline characteristics (age, gender and indication for procedure), VAS score, CBSCV grade and time for venepuncture were compared using One-way ANOVA for continuous variables and Person chi-square tests for categorical variables. For all of the statistical tests, $P < 0.05$ was considered statistically significant. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS 11.0 for Windows, SPSS Inc, Chicago, IL).

Results

During the study period, 3872 patients underwent venepuncture in the paediatric department at Qingdao Municipal Hospital, of whom 3521 were not eligible. Of 351 eligible patients, 300 were enrolled into the study (100 patients in the audiovisual distraction group, 100 patients in the intervention group, 100 patients in the control group). 29 patients refused participation and 22 patients were not offered enrolment because the research nurse was not on duty or too busy with other duties (fig. 1). All enrollees achieved the outcome measures and were included in the analysis.

Baseline characteristics

There were slight differences in patient baseline characteristics among those in the audiovisual distraction, intervention and control groups (tab. 3). Audiovisual distraction group patients were more likely than intervention group and control group patients to be nine years old (49%, 44% and 41%, respectively), and female (53%, 52% and 49%, respectively). The education status of the children was similar. The indications for

procedure were nearly identical in the three groups.

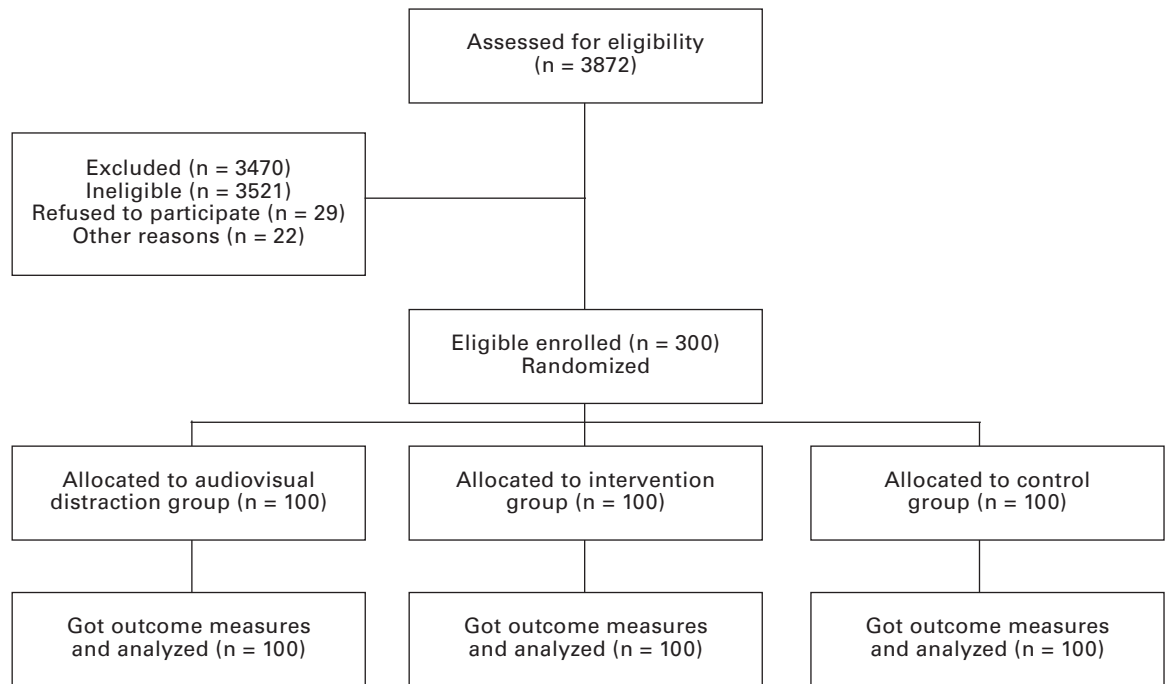
Cooperation

221 (73.67%) and 48 (16%) patients presented grade 0 and 1 cooperation, respectively. Only 31 (10.33%) patients were assessed at grade 2 (tab. 4). There was no significant difference between the audiovisual distraction and intervention groups ($\chi^2 = 2.220$, $P = 0.330 > 0.05$). The control group was significantly different ($\chi^2 = 11.141$, $P = 0.004 < 0.01$) to the intervention group, but not apparently different to the audiovisual distraction group ($\chi^2 = 5.496$, $P = 0.064 > 0.05$).

Times of venepuncture

Venepuncture was successfully performed at the first attempt in 97.0% of audiovisual distraction patients and 98.0% of intervention group patients as well as 90.0% of control group patients. There were apparent differences in times of venepuncture between the three groups ($\chi^2 = 8.000$, $P = 0.018 < 0.05$). In paired-group compari-

Figure 1
Patient flow through the study.



son, times of venepuncture showed no significant difference between the audiovisual distraction and intervention groups ($\chi^2 = <0.001, P = 1.000 >0.05$), whereas it was significantly different in the control group compared with the audiovisual distraction ($\chi^2 = 4.031, P = 0.045 <0.05$) and intervention groups ($\chi^2 = 5.674, P = 0.017 <0.05$).

Venepuncture pain

There were significant differences between the control group (VAS score: 5.22 ± 2.53) compared with the audiovisual distraction and intervention groups (VAS score: 4.55 ± 2.26 and 4.38

± 2.32 in the audiovisual distraction and intervention groups, respectively) ($P = 0.031 <0.05$) (tab. 5). No indicators of patient painful experience were significantly different in the audiovisual distraction and intervention groups, although audiovisual distraction patients were somewhat more likely to have a higher VAS score during the procedure ($P = 0.613 >0.05$). Pain score of the control group was significantly higher than the audiovisual distraction and intervention groups ($P = 0.047, 0.013 <0.05$). However, the statistical differences are not obvious in means and 95% confidence intervals (tab. 6).

Table 3
Baseline characteristics of patients.

Characteristics	Audiovisual distraction group (n = 100)		Intervention group (n = 100)		Control group (n = 100)	
	n	%	n	%	n	%
Age						
8 yrs	51	51.0	56	56.0	59	59.0
9 yrs	49	49.0	44	44.0	41	41.0
Gender						
Male	47	47.0	48	48.0	51	51.0
Female	53	53.0	52	52.0	49	49.0
Education status						
In school	100	100.0	100	100.0	100	100.0
Indication for procedure						
Pneumonia	68	68.0	57	57.0	62	62.0
Asthma	12	12.0	15	15.0	10	10.0
Encephalitis	5	5.0	9	9.0	11	11.0
Allergic purpura	8	8.0	6	6.0	9	9.0
Diarrhoea	7	7.0	13	13.0	8	8.0

Table 4
Grade of CBSCV * in school-age children of the three groups.

Grade	Audiovisual distraction group (n = 100)		Intervention group (n = 100)		Control group (n = 100)	
	n	%	n	%	n	%
0	73	73.0	81	81.0	67	67.0
1	19	19.0	15	15.0	14	14.0
2	8	8.0	4	4.0	19	19.0

* CBSCV: cooperative behaviour scale of children in venepuncture

Table 5

VAS scores in school-age children of the three groups.

Score	Audiovisual distraction group (n = 100)	Intervention group (n = 100)	Control group (n = 100)	F	P
Mean	4.55	4.38	5.22	3.505	0.031
SD	2.262	2.317	2.529		
Range	1.00–9.00	0.00–9.00	1.00–9.00		

Table 6

Multiple comparisons of VAS scores in the three groups.

Group	VAS score [Mean (95%CI)]	P
Audiovisual distraction group <i>vs</i> intervention group	4.55(0.12–8.98) <i>vs</i> 4.38 (–0.16–8.92)	0.613
Audiovisual distraction group <i>vs</i> control group	4.55(0.12–8.98) <i>vs</i> 5.22 (0.26–10.18)	0.047
Intervention group <i>vs</i> control group	4.38 (–0.16–8.92) <i>vs</i> 5.22 (0.26–10.18)	0.013

Discussion

Venepuncture is commonly seen as one of the most painful and most frequently performed invasive procedures in hospital [14]. In the paediatric population, it can be one of the most distressing events associated with medical encounters [15]. Because of a natural fear of needles, almost all children have fear, pain, and distress before and during the procedure [16, 17]. They cry, are frightened and often refuse to cooperate. Negative response and psychological suffering may lead to more difficulty and lower success rates in venepuncture. It is, therefore, necessary to develop a safe, effective and easy to administer approach to minimize suffering while facilitating the success of medical interventions.

In the past decades, most reports on pain relief in paediatric patients have suggested that the drug approaches to pain management, especially in short painful procedure, are inadequate [18]. Recent studies [15] demonstrated that EMLA cream is safe and effective in reducing pain during venous puncture in children and suggested its use as a routine procedure. Unfortunately, the onset of action of EMLA cream (application at least 60 minutes in advance) and financial restrictions limit its applicability for venepuncture in some paediatric units. Psychological support and intervention, such as encouragement, therapeutic touch and guided imagery have been demonstrated to be successful [10, 12, 19, 20] and is at present the method adopted to assure the best pain control. However, these practices have not been adopted in general in paediatric departments because nurses are often too busy to perform such time consuming procedures. Developing an effective, labour saving and easy to administer approach would be useful to alleviate pain.

Distraction is a simple, cognitive behavioural intervention that diverts attention from a stressful stimulus and focuses it onto a more pleasant one [8, 13, 21–24]. To be effective, the distraction technique must be age appropriate and it must be appealing to the recipient [25, 26]. Animated cartoons on pleasant topics have been demonstrated to be an effective focus interesting most children and seem a safe and easy to administer stimulus for distraction therapy [8, 21]. Bellieni CV et al. [8] surveyed 69 children aged 7–12 years undergo-

ing venepuncture with the use of the Oucher scale, and found that TV watching (ie watching an age appropriate cartoon on TV) was more effective than active distraction performed by their mothers. Mason et al. [8] suggested that a passive strategy (such as watching TV) might be more effective than an active one (distraction with an interactive toy) for decreasing the pain of venepuncture because the child distress interfered with their ability to interact with the distractor. Therefore, we chose cartoon films as the distractor in this study.

Our study shows that both watching cartoon film and psychological intervention can influence children's cooperation during the procedure. Even though the difference between the audiovisual distraction and control groups did not reach statistical significance ($P = 0.064$), a change in degree of cooperation from 81% (Grade 0 and 1 patients in the control group) to 92% (Grade 0 and 1 patients in the audiovisual distraction group) would be considered by most to be of clinical significance. It indicates that watching cartoon films can improve the cooperative attitude of patients as effectively as routine psychological intervention and seems to be beneficial to the further process. In our study, venepuncture times were apparently lower in the audiovisual distraction and intervention groups than the control group. It is consistent with the general idea of cooperation scaled with CBSCV.

In a former study, Curtis et al. [18] demonstrated that venepuncture in infants is a moderately painful procedure. Our results also suggest that venepuncture is a procedure that causes moderate pain in school age children. Several studies reported that audiovisual distraction and other psychological interventions could reduce pain [5, 7–13, 20, 21], but it was only recommended as a complementary approach [27, 28]. In our study, a VAS score rated at 5.22 ± 2.53 in the control group fell into the rating of 4.55 ± 2.26 in the audiovisual distraction group and 4.38 ± 2.32 in the intervention group. It shows that watching cartoon film and psychological intervention are both effective (compared with the control group, $P = 0.047, 0.013 < 0.05$), even if a reduction from 5.22 to 4.55 /4.38 is not great, and the former can pro-

vide analgesia as well as the latter ($P = 0.613 > 0.05$). Because of the characteristics of labour saving and easy to administer, audiovisual distraction (eg watching cartoon film) seems to be more suitable to clinical practice in paediatric department.

There are several limitations to our study. One limitation was the difficulty in blinding the subjects to the intervention, which may have contributed to reporting bias among parents who observed the procedure. Another limitation of this study was that the study population was a convenience sample of patients. Many school age children outside the range of 8 to 9 years of age were excluded. It is likely that these children would have been different from our study population. Therefore, further studies are needed to assess the effect of audiovisual distraction techniques in other school age children. Finally, our study is limited by the potential bias associated with the use of self reported measurement scales of pain intensity. Objective physiological markers, such as

change in pulse rate, body temperature or neuro-hormonal mediators were not studied.

In conclusion, the use of audiovisual distraction techniques was demonstrated to be effective in reducing self reported pain, improving children's cooperation and increasing success rates in venepuncture procedure as effectively as routine psychological interventions. It is highly recommended as an effective, labour saving and easy to administer analgesia and should be used in the paediatric department to help prevent pain from venepuncture in school age children.

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