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Relaxation and guided imagery do not reduce stress, pain and unpleasantness for 11 to 12-year-old girls during vaccinations

Running title: Relaxation and guided imagery during vaccinations

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Abstract

Aim

Relaxation and guided imagery is a distraction technique known to reduce discomfort during paediatric medical procedures. We examined whether its use decreased the stress experienced by 11 to 12-year-old girls receiving the human papilloma virus vaccination, as well as the intensity and unpleasantness of any pain.

Method

A randomised crossover trial was conducted with 37 girls. During the first vaccination, each girl was randomised to receive either relaxation and guided imagery or standard care. They then received the other form of care during the second vaccination. Salivary cortisol was measured before each vaccination and 30 minutes after it was administered. The girls reported pain intensity and pain unpleasantness before and directly after each vaccination and stress after each vaccination.

Results

On a group level, relaxation and guided imagery did not decrease cortisol levels, self-reported stress, pain intensity and pain unpleasantness. Salivary cortisol levels decreased significantly in both groups during the second vaccination.

Conclusion

Relaxation and guided imagery did not prove beneficial during the vaccination of 11 to 12-year-old girls and is not recommended as a regular nursing intervention. However, further research is needed into effective techniques to help children who experience pain unpleasantness in connection with needle procedures.

Key notes

- Relaxation and guided imagery is a distraction technique known to reduce discomfort during paediatric medical procedures.

- We found that its use did not decrease the stress experienced by a group of 11 to 12-year-old girls receiving the human papilloma virus vaccination, as well as the intensity and unpleasantness of any pain.
- However, further research is needed into effective techniques to help children who experience pain unpleasantness with needle procedures.

BACKGROUND

Providing young girls with the human papilloma virus (HPV) vaccination before their first sexual contact is expected to prevent cervical cancer and deaths among women all over the world (1). This initiative should draw public attention to the benefits of vaccination programmes, but the reality is quite the opposite. In general, the negative aspects of vaccination programmes receive much more publicity than the positive aspects and this may influence whether children and their parents decide whether to go ahead with vaccinations (2).

The three HPV vaccinations have been included in the Swedish childhood vaccination programme since 2010 and are part of the school health programme for 12-year-old girls. It has been reported that the majority (82%) of Swedish girls born in 2001 have received at least one dose of the HPV vaccine (3). In Denmark, compliance has been reported to be 80%, 75%, and 62%, respectively, for the three HPV vaccinations (4). Vaccinations are often associated with pain and distress by children and were found to be one of the reasons why they avoid vaccinations (5). Exposure to an acute stressor is typically followed by a release of the stress hormone cortisol. An acute stressor may be a direct threat to homeostasis, such as pain or a drop in blood pressure, or a more complex threat involving higher limbic levels, such as unpleasantness or fear.

Salivary cortisol has become a major biomarker of stress among adults and children (6) and measuring this instead of plasma is valuable and feasible when studying stress reactivity in children, as saliva collection is considered to be painless (7).

Several coping strategies are known to limit children's pain experiences in connection with vaccinations and these minimise suffering and the development of pain memories (8).

A child's ability to cope with emotions in relation to a vaccination can be explained by their individual ability to use coping strategies (9), such as the solutions that are available in school healthcare. For example, studies have demonstrated that distraction is a coping strategy that relieves needle-related pain (10, 11) and anxiety (11) and that children of school age prefer distraction techniques that give them control of their situation (12).

Uman et al (10) concluded that combining distraction and cognitive behavioural techniques was effective in decreasing anxiety and preventing negative pain experiences during needle-related procedures in children. Guided imagery is a distraction technique known to reduce discomfort during medical procedures, particularly in child healthcare, and it is recommended for children from seven-years-of-age (13).

Guided imagery is often combined with relaxation and this combination has been shown to reduce children's pain and anxiety during venipuncture (14). During relaxation and guided imagery, the child is encouraged to imagine something positive and is asked detailed questions to encourage them to engage in the fantasy (15).

Relaxation and guided imagery has recently been evaluated in a school-based screening study involving venipuncture. However, as whole school classes were matched, the study design may have influenced the result. A difference in pain unpleasantness between the school classes was shown, supporting a randomised design in further studies (15). The aim of this study was to evaluate whether relaxation and guided imagery had the potential to

reduce stress, pain intensity and pain unpleasantness in 11 to 12-year-old girls during HPV vaccinations.

METHOD

Study design

A randomised crossover trial was conducted, in which the same group of participants were given interventions of interest in sequence. Accordingly, the girls were randomised to receive either relaxation and guided imagery or standard care during the first vaccination and the other form of care during the second vaccination (16).

Participants

A total of 40 girls aged 11 to 12 years from three different schools in Western Sweden were asked to take part in the study when they received their three HPV vaccinations, which are part of the Swedish vaccination programme for girls. Of these, 37 agreed to participate in the study and three refused for unknown reasons (Figure 1). All the girls were fluent in the Swedish language. In this study, 31 of 37 girls reported that they expected the vaccination to be painful approximately two weeks before the first vaccination and, of these, nearly half (14/31, 45%) reported anticipated pain unpleasantness on a Facial Affective Scale (FAS), with a score of ≥ 0.75 . However, this also showed that many girls (13/31, 42%) did not anticipate pain unpleasantness from the vaccinations, with a FAS score of ≤ 0.47 (17).

Salivary Cortisol

Saliva was collected at baseline, before each vaccination, and 30 minutes after it took place to measure the response to the vaccination (18), using Salimetrics oral polymer swabs and tubes. Saliva samples were consecutively mailed to the laboratory at Linköping University Hospital, where they were centrifuged and stored at -20°C . The samples were analysed using a commercial enzyme immunoassay method (Salivary Cortisol Enzyme Immunoassay Kit, Salimetrics LLC, Pa, USA).

Instruments

Stress

The Verbal Rating Scale for Stress (VRSS) reports recent experience of stress, using a scale that ranges from zero for I did not feel any stress at all to five for I felt the worst stress I can think of. The girls reported their VRSS scores immediately after the procedure, reflecting their stress during the procedure (19).

Pain intensity

The Coloured Analogue Scale (CAS) is a self-reported scale that assesses a child's pain intensity, ranging from zero for no pain to ten for the worst possible pain. This scale is designed to provide gradations in colour, area and length, reflecting different values of pain intensity (20). Pain intensity was reported on two occasions during each vaccination, in conjunction with the girls' arrival at the school nurses' offices and then during the procedure. The latter was reported directly after the vaccination.

Pain unpleasantness

The Facial Affective Scale (FAS) is a self-reported scale with nine faces that assess a child's pain unpleasantness, ranging from 0.04 for the happiest feeling possible to 0.97 for the saddest feeling possible (20). Pain unpleasantness was reported on two occasions during each vaccination: when the girls arrived at the school nurses' offices, and directly after the vaccination.

Intervention

The four nurses who conducted the relaxation and guided imagery in this study received specific training about how it should be performed. The training lasted for half a day and combined theory and exercises. The technique, as described by Whitaker (14), involved combining progressive muscle relaxation and imagery. It was important that the intervention

was as identical as possible for all the girls who participated in this study. The researcher (SN) met with the school nurses who were providing the guided imagery after each data collection session and confirmed that the intervention was performed in line with the protocol. In this study, the girls were encouraged to progressively relax their muscles and think about something positive. The nurse encouraged them to engage in the fantasy by asking detailed questions about it.

Data collection

Data were collected between September 2012 and September 2013. The girls were consecutively invited and, if they accepted, they received a study number and were randomised to either relaxation and guided imagery or standard care when they underwent their first vaccination (Figure 1) using a computer programme (<http://www.randomizer.org>), Standard care was performed according to the regulations, with two school health nurses present. The nurses were instructed to talk as they normally do to children during vaccinations without any systematic relaxation or other non-pharmacological or pharmacological intervention. During the second vaccination, the girls received the other form of care from the one they received during the first vaccination. Saliva was collected before each vaccination and the girls were assessed using the CAS and FAS tools. After the vaccinations, the girls completed the VRSS, CAS and FAS tools to assess stress, pain intensity and pain unpleasantness during each vaccination. A second saliva sample was collected 30 minutes after they received the HPV immunisation.

Data analysis

The statistics were calculated using IBM SPSS Statistics for Windows, version 22. Statistical significance was considered if $p < 0.05$. The CAS and the FAS tools had been validated in earlier studies using parametric statistics (20), which led to the selection of parametric statistics in this study. Log₁₀ transformed cortisol values were used in the statistical analyses as the raw cortisol values were not normally distributed. The sample size was based on

previous studies where the study populations demonstrated statistically significant results for salivary cortisol reactivity in conjunction with procedural pain (18, 21). However, our study was further strengthened with a crossover design. The treatment effect was tested by performing a one-sample t-test on all 37 within subject differences between the two treatments (16). The cortisol samples, CAS scores, FAS scores before and during vaccination and the VRSS scores from each vaccination involving relaxation and guided imagery were compared with those involving standard care. The difference was tested by a paired t-test. A general linear model was used to investigate if the intervention influenced the children's cortisol reactivity, which was calculated by taking the cortisol response minus the cortisol baseline and then dividing it by the baseline. Cortisol reactivity was used as the dependent variable, while the intervention - relaxation and guided imagery or standard care - was used as the fixed factor. To control for the intervention being performed on two occasions and in three different schools, the first or second vaccination and the first, second or third school were used as covariates.

Ethical considerations

The benefits of the study were considered greater than the risks. Written information was provided for both the children and their parents and supplemented with verbal information that the children received at school. The voluntary nature of the study, as well as the right to withdraw from the study at any time without any explanation and consequences, was highlighted. If the children agreed to participate, the parents were asked for written consent. All participants received a cinema ticket. The study was approved by the Regional Ethical Review Board (Dnr: 466-12).

RESULTS

We collected saliva cortisol samples from 37 girls and they reported pain intensity using the CAS and anticipated and actual pain unpleasantness using the FAS before and immediately after each vaccination. Stress levels were reported immediately after each vaccination using

the VRSS. Two of the girls we approached refused to participate and one girl decided not to have the HPV vaccine (Table 1, Figure 1).

We were able to analyse 145 of the 146 saliva samples for cortisol, as one of the baseline samples was insufficient for analysis (Table 2). Before the vaccinations there was no significant difference in baseline levels between the children receiving relaxation and guided imagery and the children in the standard care group. During the first vaccinations there was no significant difference between the baseline and response cortisol levels in either of the two groups (Table 2). However, during the second vaccination, the salivary cortisol levels decreased significantly in both the relaxation and guided imagery group ($p=0.007$) and the standard care group ($p=0.013$). The general linear model showed no significant effect of the relaxation and guided imagery intervention on the girls' cortisol reactivity. Furthermore, there was no effect on the cortisol reactivity when it came to whether they were receiving their first or second vaccination or which of the three schools they came from.

On a group level, relaxation and guided imagery did not decrease self-reported stress, pain intensity or anticipated or actual pain unpleasantness (Table 1).

DISCUSSION

On a group level, cortisol levels, self-reported stress, pain intensity and anticipated or actual pain unpleasantness did not support relaxation and guided imagery as a general intervention for girls undergoing an HPV vaccination.

On the other hand, there was a significant decrease in salivary cortisol levels in response to the second vaccination and there are three possible explanations for this. The first possible explanation is the law of initial value, in which the high baseline values physiologically impaired the possibility of an increase (22). However, this is rather unlikely, as our values were comparable to the salivary cortisol values reported for healthy children in other studies

(23). Moreover, there were no significant differences between the two salivary cortisol baselines taken before the first and second vaccinations. The second, and more likely, explanation is that the children felt stressed before the vaccination and then their salivary cortisol fell as a response to the vaccination being over. However, this explanation implies that the recovery was faster during the second vaccination than the first one, when the salivary cortisol levels remained unchanged. A more rapid recovery could be explained by a better ability to cope with a situation that has been experienced before, in other words the girls became used to the HPV vaccinations, as there was only a short gap between the two injections. A third possible explanation for the decreased salivary cortisol response is that a vaccination is too mild a stressor for children aged 12 (7). To investigate stress reactivity in adolescents, a more psychological task, such as public speaking or an examination might be required (7).

On a group level, mild to moderate levels of self-reported stress and pain unpleasantness were also demonstrated during the vaccinations. However, some of the girls had high scores on the VRSS and the FAS. These results were similar to another study, where relaxation and guided imagery during venipuncture did not decrease the children's pain experience or pain unpleasantness on a group level (15). However, the results from these two Swedish populations did not support earlier findings in an Australian population, where relaxation and guided imagery reduced pain and anxiety during venipuncture in children (14).

In the current study, a mean value of above four on the CAS was shown during both of the vaccinations and, in most circumstances, this should lead to the need for a pain relieving intervention. Although HPV vaccinations have not been found to be worse than other vaccinations, the majority of parents in another study reported that their daughters experienced pain or discomfort when they received HPV vaccinations (24). However, other studies on HPV vaccinations have not highlighted pain as a big issue. For instance, a study conducted in Sweden showed that most of the school nurses who took part had been

contacted by parents who were concerned about their daughters receiving the HPV vaccination, but most of the questions were related to adverse effects of the vaccine itself, not to pain (25).

One explanation for the failed effect in this study could be that the nurses only received education in relaxation and guided imagery for half a day, which may have been too little to guarantee that they offered an identical intervention. It is important that nurses who conduct relaxation and guided imagery interventions are comfortable in using the technique and skilled in using the intervention properly. If nurses feel more competent in using the technique, they will use it more often and feel more comfortable using it (26). However, the three schools were not a significant variable in the general linear model. Another explanation could be that relaxation and guided imagery does not suit everyone and should only be offered to those who find the intervention suitable.

One limitation to the study is that no power analysis was performed. The sample size was based on previous findings (18, 21) and it is possible that the sample size was too small to accurately detect significant changes related to the relaxation and guided imagery. The study should, therefore, be repeated in a larger population. A weakness of this study was that the girls were not asked about earlier experiences of needle-related procedures. The fact that only girls participated in the study could also be considered a weakness. On the other hand, the study was strengthened by the crossover design and the fact that there were no dropouts during the vaccinations. Finally, the results are limited to young adolescents. However, this study aimed to find a coping strategy for HPV vaccinations, and most children who receive HPV vaccinations are of the same age as the participants in this study.

CONCLUSION

The findings of this study do not support relaxation and guided imagery as a standardised intervention during the vaccination of 11 to 12-year-old girls. Because some children

experienced anticipatory pain unpleasantness in connection with needle procedures, there is a need to further investigate effective techniques to help these children. The group level effect of relaxation and guided imagery should probably be evaluated in a more stressful situation and with a higher level of pain unpleasantness than a vaccination.

Abbreviations

Coloured Analogue Scale = CAS

Facial Affective Scale = FAS

Human papilloma virus = HPV

Verbal Rating Scale for Stress = VRSS

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Conflict of interest

The authors do not have any potential conflicts of interest to declare.

References

1. Jit M, Brisson M, Portnoy A, Hutubessy R. Cost-effectiveness of female human papillomavirus vaccination in 179 countries: a PRIME modelling study. *Lancet Glob Health* 2014; 2:e406-14
2. Andre FE, Booy R, Bock HL, Clemens J, Datta SK, John TJ, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. *Bull World Health Organ* 2008; 86:140-6
3. Folkhälsomyndigheten. <http://www.folkhalsomyndigheten.se/amnesomraden/statistik-och-undersokningar/vaccinationsstatistik/statistik-for-hpv-vaccinationer/2014>
4. Widgren K, Simonsen J, Valentiner-Branth P, Molbak K. Uptake of the human papillomavirus-vaccination within the free-of-charge childhood vaccination programme in Denmark. *Vaccine* 2011; 29:9663-7
5. Taddio A, Ipp M, Thivakaran S, Jamal A, Parikh C, Smart S, et al. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine* 2012; 30:4807-12
6. Ivars K, Nelson N, Finnstrom O, Mörelius E. Nasopharyngeal suctioning does not produce a salivary cortisol reaction in preterm infants. *Acta Paediatr* 2012; 101:1206-10
7. Gunnar MR, Talge NM, Herrera A. Stressor paradigms in developmental studies: what does and does not work to produce mean increases in salivary cortisol. *Psychoneuroendocrinology* 2009; 34:953-67
8. Taddio A, Appleton M, Bortolussi R, Chambers C, Dubey V, Halperin S, et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. *CMAJ* 2010; 182:E843-55
9. Lazarus RS. Emotions and interpersonal relationships: toward a person-centered conceptualization of emotions and coping. *J Pers* 2006; 74:9-46
10. Uman LS, Birnie KA, Noel M, Parker JA, Chambers CT, McGrath PJ, et al. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev* 2013; 10:CD005179

11. Nguyen TN, Nilsson S, Hellstrom AL, Bengtson A. Music therapy to reduce pain and anxiety in children with cancer undergoing lumbar puncture: a randomized clinical trial. *J Pediatr Oncol Nurs* 2010; 27:146-55
12. Kristjansdottir O, Kristjansdottir G. Randomized clinical trial of musical distraction with and without headphones for adolescents' immunization pain. *Scand J Caring Sci* 2011; 25:19-26
13. Pincus D, Sheikh AA. Imagery for pain relief. New York: Routledge; 2009
14. Whitaker B. The effects of distraction and Guided imagery on procedural fear and pain in children. Australia: University of Ballarat; 2002
15. Forsner M, Norstrom F, Nordyke K, Ivarsson A, Lindh V. Relaxation and Guided imagery used with 12-year-olds during venipuncture in a school-based screening study. *J Child Health Care* 2014; 18:241-52
16. Altman DG. Practical Statistics for Medical Research: Chapman & Hall/CRC; 1990
17. Nilsson S, Finnström B, Mörelius E, Forsner M. The Facial Affective Scale (FAS) as a predictor for pain unpleasantness when children undergo immunizations. *Nursing Research and Practice* 2014; 2014:628198
18. Mörelius E, Theodorsson E, Nelson N. Stress at three-month immunization: parents' and infants' salivary cortisol response in relation to the use of pacifier and oral glucose. *Eur J Pain* 2009; 13:202-8
19. Alfven G, Nilsson S. Validity and reliability of a new short verbal rating scale for stress for use in clinical practice. *Acta Paediatr* 2014; 103:e173-5
20. McGrath PA, Seifert CE, Speechley KN, Booth JC, Stitt L, Gibson MC. A new analogue scale for assessing children's pain: an initial validation study. *Pain* 1996; 64:435-43
21. Kleberg A, Warren I, Norman E, Mörelius E, Berg AC, Mat-Ali E, et al. Lower stress responses after Newborn Individualized Developmental Care and Assessment Program care during eye screening examinations for retinopathy of prematurity: a randomized study. *Pediatrics* 2008; 121:e1267-78

22. Wilder J. The law of initial value in neurology and psychiatry; facts and problems. *Ment Dis.* 1957;73-86
23. Sieh D, Visser-Meily JM, Oort FJ, Meijer AM. The diurnal salivary cortisol pattern of adolescents from families with single, ill and healthy parents. *J Psychosom Res* 2012; 72:288-92
24. Reiter PL, Brewer NT, Gottlieb SL, McRee AL, Smith JS. How much will it hurt? HPV vaccine side effects and influence on completion of the three-dose regimen. *Vaccine* 2009; 27:6840-4
25. Grandahl M, Tyden T, Rosenblad A, Oscarsson M, Neveus T, Stenhammar C. School nurses' attitudes and experiences regarding the human papillomavirus vaccination programme in Sweden: a population-based survey. *BMC public health* 2014; 14:540
26. MacLaren JE, Cohen LL, Larkin KT, Shelton EN. Training nursing students in evidence-based techniques for cognitive-behavioral pediatric pain management. *J Nurs Educ* 2008; 47:351-8

Figure 1 The CONSORT flow diagram

Table 1. Statistics of self-reports

Comparison	Mean (SD) 1	Mean (SD) 2	p-value
VRSS during RGI and VRSS during SC	1.53 (1.15)	1.54 (1.03)	1.0
CAS before RGI and CAS before SC	2.18 (2.89)	1.86 (2.46)	.65
CAS during RGI and CAS during SC	4.26 (2.20)	4.80 (2.36)	.23
CAS differences* RGI and CAS differences* SC	2.08 (3.24)	2.94 (2.78)	.23
FAS before RGI and FAS before SC	0.58 (0.23)	0.64 (0.19)	.06
FAS during RGI and FAS during SC	0.61 (0.20)	0.61 (0.22)	.78
FAS differences* RGI and FAS differences* SC	0.02 (0.20)	-0.02 (0.13)	.28

RGI=Relaxation and Guided Imagery

SC=Standard care

*=The individual differences between before and during the vaccination

Table 2. Raw salivary cortisol levels (nmol/L) in relation to each vaccination

Vaccination number	Intervention	n	Saliva sampling	Salivary cortisol nmol/L Mean (SD)	p-value
1	RGI	16	Baseline	6.6 (4.0)	.58
			Response	7.6 (6.4)	
	SC	20	Baseline	8.4 (11.4)	.52
			Response	12.4 (37.0)	
2	RGI	20	Baseline	7.2 (5.1)	.007
			Response	4.2 (2.4)	
	SC	17	Baseline	7.9 (4.1)	.013
			Response	5.6 (3.3)	

RGI=Relaxation and Guided Imagery

SC=Standard care