母乳香味是否有安 撫早產兒的效果?

戴仲宜 2017.7.18











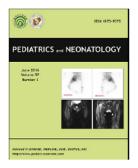




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ORIGINAL ARTICLE

Effects of Breast Milk and Vanilla Odors on Premature Neonate's Heart Rate and Blood Oxygen Saturation During and After Venipuncture



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Ranking: Pediatrics 78/121

背景

- GA 26週後的早產兒已經有痛覺
- 非藥物性疼痛緩解措施
 - sense of taste: 糖水、母乳
 - sense of smell: 母乳
 - sense of hearing: 音樂
 - sense of touch: 撫觸、袋鼠護理
 - sense of sight: 燈光

文章介紹

<u>Background</u>: Different studies have shown that the use of olfactory stimuli during painful medical procedures reduces infants' response to pain. The main purpose of the current study was to investigate the effect of breast milk odor and vanilla odor on premature infants' vital signs including heart rate and blood oxygen saturation during and after venipuncture <u>Methods</u>: A total of 135 preterm infants were randomly selected and divided into three groups of control vanilla odor and breast milk odor. Infants in the breast milk group and the vanilla group were exposed to breast milk odor and vanilla odor from 5 minutes prior to sampling until 30 seconds after sampling.

<u>Results:</u> The results showed that <u>breast milk odor</u> has a significant effect on the changes of neonatal heart rate and blood oxygen saturation during and after venipuncture and decreased the variability of premature infants' heart rate and blood oxygen saturation. Vanilla odor has no significant effect on premature infants' heart rate and blood oxygen saturation.



步驟1 研究探討的問題為何?

研究族群/問題 (P)

Gestational age of 28-34 weeks and postnatal age of 3-28 days

介入措施(I)

Breast milk odor

比較 (C)

Vanilla odor, Smell placebo

結果 (O)

Heart rate
Oxygen saturation



步驟 2:研究的品質有多好(內在效度)?

招募(Recruitment) - 受試者是否具有代表性?

最好的狀況是?

我們是否知道病人族群為何(收案場所、納入 / 排除 條件)?在理想情況下,納入本研究之受試者應具有 連續性(有時為隨機取樣),了解符合收案條件的對象 日簽署同意書。

我可以在哪裡找到這些資訊?

在文章的方法(Methods)章節的開頭,可以找到本研 究篩選病人的方式。

評讀結果:★是 □否

口不清楚

說明:

收案場所

The current study was conducted at the NICU of Al-Zahra Hospital, which is affiliated to Tabriz University of Medical Sciences, Tabriz, Iran. This study was approved by the Ethics Committee of Tabriz University of Medical Sciences, and parents' consent was obtained. Sample size was

Inclusion Criteria

3-28 days. They were breast-fed and had no congenital or systemic abnormalities. They had a previous venipuncture experience and had physiological stability. Their Apgar scores were higher than 7 at 5 minutes after birth. Lack of intraventricular hemorrhage, lack of periventricular leukomalacia, no need for surgery, and not receiving analgesic were the other requirements. Infants who were eligible for

IRB & Inform Consent

分派(Allocation) - 分派方式是否隨機且具隱匿性...?

最好的狀況是?

最理想的方式是以中央電腦進行隨機分配,此方式常用於多中心試驗,而較小型的試驗可由獨立人員(如醫院藥師)「監督」隨機分配的過程。

我可以在哪裡找到這些資訊?

在文章的方法(Methods)段落中,可以找到病人分配到不同組的方式,以及隨機分配是否具隱匿性;作者應說明隨機分派方式「監督」或屏蔽(masking)的方式(如使用外觀相同的安慰劑、或給予一個「假的」治療 sham therapy)。

評讀結果:★是 □否 □不清楚 說明:

were the other requirements. Infants who were eligible for inclusion in the study were randomly assigned into three groups using the Rand List software. Each group had 45

to 30 seconds after the end of sampling. <u>Infants in the</u> control group were exposed to smell placebo. For exposing

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... 每個組別,在研究開始時的情況是否相同?

最好的狀況是?

若隨機分配順利,各組研究對象的條件應是相近、可互相比較的。每組研究對象的基本條件越相近越好。應有指標可確認各組研究對象之間的差異是否達到統計上顯著的差異(如 p 值)。

我可以在哪裡找到這些資訊?

在文章的結果(Results) 段落中,可以找到「研究對象基本資料」的表格,裡面包括幾個可能影響隨機分配的各組研究結果之重要變項(如年齡、風險因子等)。如果作者沒有用表格呈現,在結果章節的第一段中,可能可以找到各組研究對象特性的說明。

評讀結果:★是 □否 □不清楚 說明:

Table 1 Demographic characteristics of infants in breast milk odor, vanilla odor, and control groups.

Group		Breast milk odor	Vanilla odor	Control	р
Sex	Girl	18 (40)	30 (66.7)	25 (55.4)	0.16
	Boy	27 (60)	15 (33.3)	20 (44.6)	
Gestational age		31.64 ± 2.1	30.93 ± 2	31.46 ± 1.96	0.22
(wk)					
Age (d)		10.03 ± 7.08	11.38 \pm 7.06	10.60 ± 7.89	0.89
Birth weight (g)		1566.9 \pm 414.89	1505.3 \pm 409.12	1569.8 \pm 405.93	0.17
Weight in sampling		1575.6 \pm 322.93	1587.8 ± 365.84	1578.4 ± 354.63	0.175
day (g)					



維持(Maintenance) - 各組是否給予相同的治療?					
最好的狀況是?	我可以在哪裡找到這些資訊?				
各研究組別之間,除了對病人的介入之外,其餘的治	在文章的 方法 段落中,可以找到各組詳細的治療方式				
療應完全相同(即為了執行本研究所增加的治療、檢	(如追蹤時間表、研究中可以使用的額外治療),在				
驗或評估應相同)。	結果 段落中,應該也可以找到更進一步的資訊。				

評讀結果:□是 □否 實不清楚 說明:

respectively, from 5 minutes prior to the start of sampling to 30 seconds after the end of sampling. Infants in the control group were exposed to smell placebo. For exposing infants to the odors, a clean cotton ball dipped in breast milk or vanilla or placebo was placed 1 mm far from their noise. Infants of the vanilla group were familiarized with vanilla odor by a 10-g clean cotton ball dipped in 10 drops of

... 是否有足夠的追蹤(Follow up) ?

最好的狀況是?

研究中流失(無法繼續追蹤)的病人,最好少於 20%。 病人應依照隨機分配的組別進行統計分析(即「治療

意向分析法 」Intention – to-treat , ITT analysis)。

我可以在哪裡找到這些資訊?

在文章的結果段落中,應可以找到接受隨機分配的病 人人數,以及實際進行分析的人數。有時會有流程圖 (如果沒有,可自行繪製)。

評讀結果:實是 口否 口不清楚 說明:

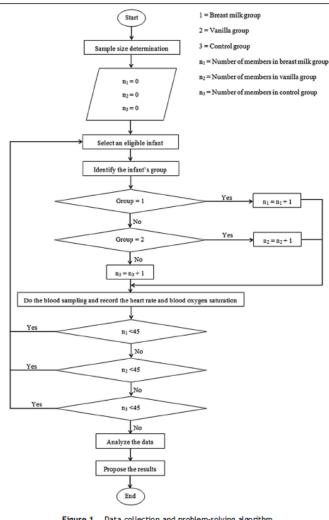


Figure 1 Data collection and problem-solving algorithm.

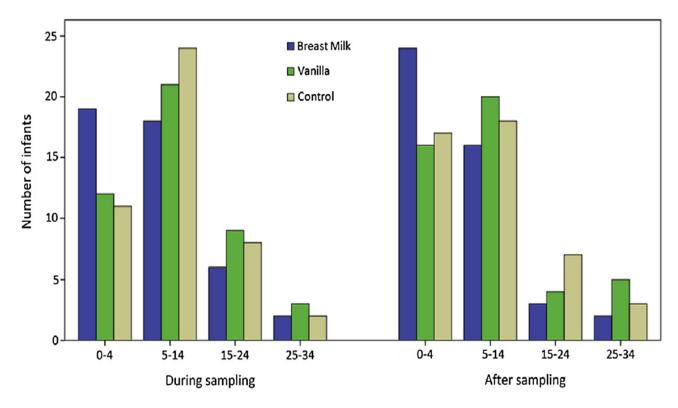


Figure 2 Heart rate variations during and after sampling (X axis shows changes in heart beats/min and Y axis shows number of infants).



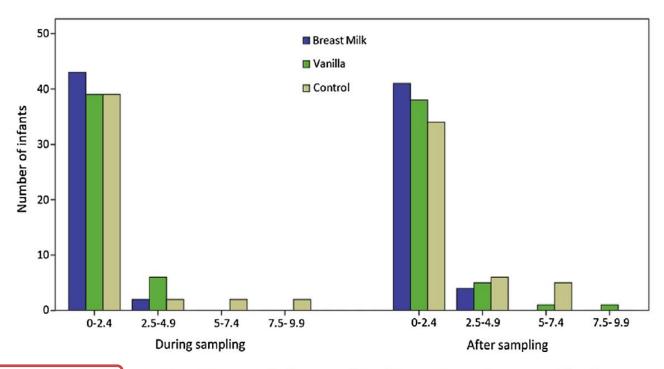


Figure 3 Blood oxygen saturation variations during and after sampling (X axis shows changes in blood oxygen saturation and Y axis shows number of infants).

....

評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)?

最好的狀況是?	我可以在哪裡找到這些資訊?
在客觀結果(如:死亡)方面,盲法的重要性較低,但	在文章的 方法 段落中,可以找到研究結果的評估方
在主觀結果(如:症狀或功能)方面,評估者維持盲法	式,以及評估者是否知道病人接受何種治療。
非常重要。	

評讀結果:□是 ★ 古 □不清楚 說明:

respectively, from 5 minutes prior to the start of sampling to 30 seconds after the end of sampling. Infants in the control group were exposed to smell placebo. For exposing infants to the odors, a clean cotton ball dipped in breast milk or vanilla or placebo was placed 1 mm far from their noise. Infants of the vanilla group were familiarized with vanilla odor by a 10-g clean cotton ball dipped in 10 drops of vanilla solution. The vanilla solution had 0.64% vanilla (by mass), and for its preparation, vanilla was mixed with glycerin using a hot plate stirrer at 300 rpm [the hot plate

stirrer was obtained from Heidolph Group (model MR 3001 K; Schwabach, Germany); vanilla and glycerin were obtained from Merck KGaA Chemical Company (Darmstadt, Germany)]. The cotton balls were placed in incubators 10 cm from the infants' nose 12 hours prior to sampling. Sampling was obtained from 7:30 AM to 8:30 AM. Previous studies showed that the time of painful procedures may affect the intensity of pain, ²³ so the sampling time was similar for all infants. During the procedure, all infants were placed in a 37°C warmer. The heart rate and blood



步驟 3: 研究結果的意義為何?

Table 2 Changes in heart rate and blood oxygen saturation of infants in breast milk odor, vanilla odor, and control groups during and after sampling.

Group	During sampling		After sampling		
	Heart rate changes (beats/min)	Blood oxygen saturation changes (%)	Heart rate changes (beats/min)	Blood oxygen saturation changes (%)	
Breast milk odor Vanilla odor	5.9111 ± 0.4871 9.4444 ± 0.5334	$\begin{array}{c} 0.3578 \pm 0.07334 \\ 0.9178 \pm 0.2696 \end{array}$	$\begin{array}{c} \textbf{4.7556} \pm \textbf{0.2963} \\ \textbf{9.0444} \pm \textbf{0.15742} \end{array}$	$\begin{array}{c} 0.5111 \pm 0.09606 \\ 1.0689 \pm 0.09296 \end{array}$	
Control p	9.6222 ± 1.0171 0.021	1.1422 ± 0.28232 0.014	8.8667 ± 0.9447 0.011	1.489 ± 0.1163 0.04	





Cochrane Database of Systematic Reviews

Non-pharmacological management of infant and young child procedural pain (Review)

Pillai Riddell RR, Racine NM, Gennis HG, Turcotte K, Uman LS, Horton RE, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Lisi DM



Data collection and analysis

Study quality ratings and risk of bias were based on the Cochrane Risk of Bias Tool and GRADE approach. We analysed the standardized mean difference (SMD) using the generic inverse variance method.

Main results

Sixty-three studies, with 4905 participants, were analysed. The most commonly studied acute procedures were heel-sticks (32 studies) and needles (17 studies). The largest SMD for treatment improvement over control conditions on pain reactivity were: non-nutritive sucking-related interventions (neonate: SMD -1.20, 95% CI -2.01 to -0.38) and swaddling/facilitated tucking (preterm: SMD -0.89; 95% CI -1.37 to -0.40). For immediate pain regulation, the largest SMDs were: non-nutritive sucking-related interventions (preterm: SMD -0.43; 95% CI -0.63 to -0.23; neonate: SMD -0.90; 95% CI -1.54 to -0.25; older infant: SMD -1.34; 95% CI -2.14 to -0.54), swaddling/facilitated tucking (preterm: SMD -0.71; 95% CI -1.00 to -0.43), and rocking/holding (neonate: SMD -0.75; 95% CI -1.20 to -0.30). Fifty two of our 63 trials did not report adverse events. The presence of significant heterogeneity limited our confidence in the findings for certain analyses, as did the preponderance of very low quality evidence.

Authors' conclusions

There is evidence that different non-pharmacological interventions can be used with preterms, neonates, and older infants to significantly manage pain behaviors associated with acutely painful procedures. The most established evidence was for non-nutritive sucking, swaddling/facilitated tucking, and rocking/holding. All analyses reflected that more research is needed to bolster our confidence in the direction of the findings. There are significant gaps in the existing literature on non-pharmacological management of acute pain in infancy.

問題討論

早產兒執行侵入性處置後,使用母乳香味進 行嗅覺刺激是否有安撫效果?



綠(同意):0人 黃(需討論):8人 紅(不同意):15人



Thank you for your attention~

