

doi: 10.13241/j.cnki.pmb.2023.06.026

## EarWell 耳矫治器对新生儿耳廓畸形的效果及其预后不良影响因素分析\*

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**摘要目的:**探讨 EarWell 耳矫治器对新生儿耳廓畸形的效果及其预后不良影响因素。**方法:**选取我院 2019 年 3 月到 2022 年 3 月收治的 60 例(共 78 耳)耳廓畸形新生儿作为研究对象,依照患儿年龄进行分组,将年龄 $\leq 7$  d 的 16 例(21 耳)患儿分为 A 组,8-14 d 的 21 例(26 耳)分为 B 组,15-28 d 的 23(31 耳)分为 C 组,对所有患儿采取 EarWell 耳矫治器治疗,对比不同组别患儿新生儿耳廓畸形的治疗总有效率,并发症和矫治时间。通过复查随访评价患儿预后情况,将 48 例(60 耳)预后良好的患儿分为预后良好组,将 12 例(18 耳)预后不良的患儿分为预后不良组,对比两组患儿临床相关资料。最后,采用 logistic 回归分析分析 EarWell 耳矫治器对新生儿耳廓畸形治疗预后不良的影响因素。**结果:**三组患儿治疗总有效率差异显著,A 组(100.00%)高于 B 组(88.46%)与 C 组(64.52%)( $P<0.05$ );A 组患儿并发症发生率为 14.29%,B 组为 15.38%,C 组为 19.35%,组间对比有差异( $P>0.05$ );预后良好组与预后不良组患儿性别、畸形部位对比无差异( $P>0.05$ ),预后良好组与预后不良组患儿年龄、耳廓畸形 Max 分型、外耳道闭锁分级以及容貌耳长差值对比差异显著( $P<0.05$ );logistic 回归分析结果显示,年龄、耳廓畸形 Max 分型为新生儿耳廓畸形治疗预后不良的独立影响因素( $P<0.05$ )。**结论:**EarWell 耳矫治器对于新生儿耳廓畸形矫治效果显著,并发症发生率较低,且年龄越小矫治效果越好。年龄、耳廓畸形 Max 分型为耳廓畸形新生儿的预后不良的独立影响因素,临床上针对此类患儿需采取一定预防措施,预防预后不良现象的发生。

**关键词:**EarWell 耳矫治器;新生儿;耳廓畸形;预后不良;影响因素

中图分类号:R764.7 文献标识码:A 文章编号:1673-6273(2023)06-1131-05

## Analysis of The Effect of Earwell Ear Appliance on Auricle Malformation of Newborn and Its Adverse Prognostic Factors\*

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**ABSTRACT Objective:** To explore the effect of earwell ear appliance on neonatal auricle malformation and its adverse prognostic factors. **Methods:** 60 newborns (78 ears in total) with auricle malformation admitted to our hospital from March 2019 to March 2022 were selected as the study objects. They were grouped according to the age of the children. 16 infants (21 ears) with the age  $\leq 7$  d were divided into group A, 21 infants (26 ears) with the age of 8-14 d were divided into group B, and 23 infants (31 ears) with the age of 15-28 d were divided into group C. all the infants were treated with earwell ear appliance. The total effective rate of the treatment of neonatal auricle malformation in different groups of children was compared, Complications and treatment time. The prognosis of children was evaluated by review and follow-up, 48 children (60 ears) with good prognosis were divided into good prognosis group, and 12 children (18 ears) were divided into poor prognosis group, and the clinical relevant data of the two groups were compared. Finally, logistic regression analysis was used to analyze the factors affecting the poor prognosis of earwell ear appliance in the treatment of neonatal auricle malformations. **Results:** The total effective rate of the three groups was higher in group A (100.00%) than in group B (88.46%) and group C (64.52%) ( $P<0.05$ ); The complication rate of children in group A was 14.29%, group B was 15.38%, and group C was 19.35. There was no difference between the two groups ( $P>0.05$ ); There was no difference between the good prognosis group and the poor prognosis group in terms of gender and deformity site ( $P>0.05$ ). There were differences between the good prognosis group and the poor prognosis group in terms of age, Max classification of auricle malformation, external auditory canal atresia classification and facial ear length difference ( $P<0.05$ ); The results of logistic regression analysis showed that age and Max classification of auricle malformation were independent factors affecting the poor prognosis of neonatal auricle malformation treatment ( $P<0.05$ ). **Conclusion:** Earwell ear appliance has a effect on the correction of auricle deformity of newborns, with a low incidence of complications, and the younger the age, the better the correction effect. Age and Max classification of auricle malformation are independent factors affecting the poor prognosis of newborns with auricle malformation. In clinical practice, certain preventive measures should be taken to prevent the occurrence of

\* 基金项目:江苏省 2017 年科教强卫项目(QNRC2016200)

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(收稿日期:2022-08-08 接受日期:2022-08-30)

poor prognosis.

**Key words:** Earwell ear appliance; Newborn; Auricle deformity; Poor prognosis; Influence factor

**Chinese Library Classification(CLC):** R764.7 **Document code:** A

**Article ID:**1673-6273(2023)06-1131-05

## 前言

先天性耳廓畸形是当前新生儿常见的疾病,畸形可表现为大小、形态和位置不同,发生在双侧或单侧<sup>[1]</sup>。当前临床上将耳廓畸形分为结构畸形和形态畸形两种,其中耳廓形态畸形主要指的是耳廓主体软骨支架大多完整,但是因外力作用导致耳廓形态出现异常,耳廓结构畸形主要指耳廓的皮肤和软骨异常<sup>[2]</sup>。耳作为五官的重要部分,若耳廓外观畸形会对面容产生直接影响,可能导致患儿心理上的痛苦和自卑,而且严重耳廓畸形也会对患儿听力产生影响,从而影响患儿的身心健康,因此耳廓畸形的治疗具有重要价值<sup>[3]</sup>。以往临床上针对耳廓畸形多采取手术治疗,当前手术矫治技术也较成熟,但由于新生儿年龄较小,手术实施要等到患儿6岁左右,而且还存在一定麻醉风险<sup>[4]</sup>。随着临床医学发展,非手术治疗耳廓畸形逐渐进入人们的视野,国外发达国家也逐渐展开此方面研究,患儿通过耳廓矫治得到了显著的治疗效果,逐渐被广泛应用到临床<sup>[5]</sup>。因此,如何最大程度的减少新生儿的痛苦成为当前研究的热点话题<sup>[6]</sup>。EarWell耳廓矫形器是应用医用聚氨酯类热塑性弹性体材料,

具有一定韧度,而且质地较为柔软,对婴儿皮肤无致敏、无刺激,能够保持形态<sup>[7,8]</sup>。但临床研究发现<sup>[9,10]</sup>,EarWell耳廓矫形器对先天性耳廓畸形的治疗依然会存在大量预后不良现象,影响患儿耳廓结构、稳定性等。因此,为了提升EarWell耳廓矫形器对新生儿耳廓畸形的治疗效果,本研究选取我院2019年3月到2022年3月收治的60例(共78耳)耳廓畸形新生儿作为研究对象,探讨EarWell耳廓矫治器对新生儿耳廓畸形的效果及其预后不良影响因素,具体报道如下。

## 1 资料与方法

### 1.1 一般资料

选取我院2019年3月到2022年3月收治的60例(共78耳)耳廓畸形新生儿作为研究对象,依照患儿年龄进行分组,将年龄 $\leq 7$  d的16例(21耳)患儿分为A组,8-14 d的21例(26耳)分为B组,15-28 d的23(31耳)分为C组。三组患儿除年龄外,性别、平均治疗时间、耳廓畸形Max分型对比无明显差异( $P>0.05$ ),可以进行对比分析。如表1所示。本研究经我院伦理委员会批准。

表1 三组患儿一般资料对比

Table 1 Comparison of general data in the three pediatric groups

Groups	n	Ear number	Gender (male / female)	Average age (d)	Mean treatment duration (d)	Max classification(ear)	
						I	II
Group A	16	21	9/7	4.32±0.92	27.64±4.34	11	10
Group B	21	26	12/9	11.35±2.89	27.65±6.37	13	13
Group C	23	31	13/10	21.36±5.87	28.15±5.48	14	17
$\chi^2/F$	-	-	0.201	113.287	0.971	1.760	
<i>P</i>	-	-	0.902	0.001	0.829	0.779	

### 1.2 纳入标准与排除标准

**纳入标准:**确诊为耳廓畸形;耳廓畸形Max分型为I-II型<sup>[11]</sup>;年龄在1-28 d的新生儿;未合并重大基础疾病;无皮肤病和感染病的单侧或双侧耳廓畸形;耳周皮肤完整;畸形为杯状耳、耳廓畸形或隐耳其中一种;家长对本研究知情并签署同意书。

**排除标准:**耳廓畸形严重不能佩戴耳廓矫治器者;年龄 $> 28$  d;合并重大基础或先天性疾病;无法耐受矫正过程;治疗过程中失访;耳周具有过敏情况或皮肤溃疡者。

### 1.3 方法

**EarWell耳廓矫治器治疗方法:**应用美国EarWell耳廓矫形器依照患儿畸形类型进行针对性塑形,每周进行复诊1次,并依照畸形情况调整矫正器位置,若形态满意则持续佩戴一周,若对初期矫正效果不满意需连续佩戴3周,若仍不理想需判定为治疗无效结束矫正治疗。

3个月对所有患儿进行复查随访,对其进行预后评估,具体方法为:经查相关文献制定再造耳评价量表,并经专家审

核通过后与健侧比较,其中包括结构(45分),耳廓稳定性(12分),耳廓位置(24分),局部瘢痕情况(9分),耳廓皮肤颜色(10分),将评分 $< 75$ 分的患儿分为预后不良组,将评分 $\geq 75$ 分的患儿分为预后良好组<sup>[12]</sup>。

收集两组患儿一般临床资料,其中包括性别、年龄、耳廓畸形Max分型、畸形部位、外耳道闭锁分级等相关临床信息,并对差异具有统计学意义的项目采取logistic回归分析。

### 1.4 观察指标与疗效评价

**观察指标:**观察三组患儿在治疗过程中出现的皮肤溃疡、皮肤感染、皮疹等并发症。

**疗效评价:**治疗后耳廓外形矫治到正常状态为显效;耳廓外形与矫正之前或健侧耳相比明显改善,但是没有达到正常外形为有效;与矫正之前对比无明显改善为无效。总有效率=显效率+有效率<sup>[13]</sup>。

### 1.5 统计学方法

采取统计学软件SPSS 23.0对本研究数据进行分析,计数

资料以例数 / 百分比(n/%)表示,进行  $\chi^2$  检验;符合正态分布的计量资料用均数 $\pm$ 标准差( $\bar{x}\pm s$ )表示,采用 F/t 检验;采用 logistic 回归分析分析 EarWell 耳矫治器对新生儿耳廓畸形治疗预后不良的影响因素;以  $P<0.05$  为差异有统计学意义。

## 2 结果

### 2.1 不同组别患儿新生儿耳廓畸形的治疗总有效率对比

三组患儿治疗总有效率差异显著,A组(100.00%)明显高于B组(88.46%)与C组(64.52%)( $P<0.05$ ),如表2所示。

表2 不同组别患儿新生儿耳廓畸形的治疗总有效率对比(耳,%)

Table 2 Total response rate comparison of neonatal auricular deformity in different groups (ear, %)

Groups	n	Ear number	Excellence	Valid	Invalid	Total effective rate
Group A	16	21	13(61.90)	8(38.10)	0(0.00)	21(100.00)
Group B	21	26	14(53.85)	9(34.62)	3(11.54)	23(88.46)
Group C	23	31	11(35.48)	9(29.03)	11(35.48)	20(64.52)*#
$\chi^2$	-	-	-	-	-	11.790
<i>P</i>	-	-	-	-	-	0.003

Note: Compared with group A, \* $P<0.05$ . Compared with group B, # $P<0.05$ .

### 2.2 不同组别患儿新生儿耳廓畸形治疗后并发症对比

A组患儿并发症发生率为14.29%,B组为15.38%,C组

为19.35%,组间对比无差异( $P>0.05$ ),如表3所示。

表3 不同组别患儿新生儿耳廓畸形治疗后并发症对比(耳,%)

Table 3 Comparison of complications after auricular deformity in children in different groups (ear, %)

Groups	n	Ear number	Skin ulcer	Skin infection	Erythra	Grand total
Group A	16	21	1	0	2	3(14.29)
Group B	21	26	2	0	2	4(15.38)
Group C	23	31	4	1	1	6(19.35)
$\chi^2$	-	-	-	-	-	0.280
<i>P</i>	-	-	-	-	-	0.870

### 2.3 预后良好组与预后不良组患儿一般临床情况对比

预后良好组与预后不良组患儿性别、畸形部位对比无差异( $P>0.05$ ),预后良好组与预后不良组患儿年龄、耳廓畸形 Max 分型、外耳道闭锁分级以及容貌耳长差值对比差异显著( $P<0.05$ ),如表4所示。

### 2.4 EarWell 耳矫治器对新生儿耳廓畸形治疗预后不良的影响因素分析

对单因素分析具有统计学差异指标进行赋值后,logistic 回归分析结果显示,年龄、耳廓畸形 Max 分型为新生儿耳廓畸形治疗预后不良的独立影响因素( $P<0.05$ ),如表5所示。

## 3 讨论

耳作为重要的五官之一,结构较为复杂,属于立体三维结构,耳廓除了耳垂无软骨之外,其余的由软骨组成,并呈漏斗或贝壳形态<sup>[14]</sup>。耳廓外形是否美观会影响到整体面容的美观,并且在一定程度上也比其他五官畸形明显,严重者会造成儿童听力障碍<sup>[15]</sup>。但目前我国对于先天性耳廓畸形的报道较少,在普查工作或出生缺陷调查,多数医护人员更多的重视功能上的异常,却忽视形态畸形所产生的问题,特别是耳廓的形态畸形<sup>[16,17]</sup>。随着临床医学发展,越来越多医生推荐对新生儿耳廓畸形进行早期无创矫治,以往临床上所用的矫治材料主要包括绷带、胶

带、可塑性合成物等,来达到对耳轮和耳廓的重塑,但由于材料较为复杂,且会增加患儿耳廓皮肤损伤情况,严重时还会造成感染,影响患儿治疗依从性,进而影响治疗效果<sup>[19,20]</sup>。EarWell 耳矫治器属于硅胶材料制成,应用也较方便、简单,受到了越来越多临床学者推广<sup>[21]</sup>。因此,本研究对我院耳廓畸形新生儿采取 EarWell 耳矫治器治疗,并分析其预后不良影响因素,希望能够为临床提供参考意见。

本研究结果表明,三组患儿治疗总有效率差异显著,A组(100.00%)明显高于B组(88.46%)与C组(64.52%)( $P<0.05$ )。由此证明,新生儿年龄越大 EarWell 耳矫治器的治疗效果越差,与尚海琼等<sup>[22]</sup>研究相似。尚海琼等研究针对先天性耳廓畸形患儿采取 EarWell 耳矫治器进行治疗,最终发现,出生后 42 d 以上的婴儿治疗总有效率明显低于出生 42 d 之内的婴儿。这主要是因为,对于新生儿来说,出生后 72 h 之内,循环系统之中的技术水平会呈现一个明显峰值,软骨中透明质酸浓度会受到雌激素水平影响而逐渐增加,软骨的可塑性和延展性也需要透明质酸<sup>[23]</sup>。而且,随着新生儿出生 6 周之后雌激素水平也逐渐恢复正常,软骨的可塑性和韧性也逐渐降低,从而降低矫正效果<sup>[24]</sup>。另外,也有研究发现<sup>[25]</sup>,耳廓畸形在新生儿身体发育过程中会产生不断的变化,尤其是在新生儿出生 2 周之内,一部分耳廓畸形能够得到自我纠正,但是目前的自愈条件尚不

表 4 预后良好组与预后不良组患儿一般临床情况对比

Table 4 Comparison of the general clinical conditions of children with good prognosis group and poor prognosis group

Classification	Good-prognosis group of 48 patients (60 ear)	Poor prognosis group of 12 patients( 18 ear )	$\chi^2/t$	<i>P</i>
Gender (n)				
Male	26	8	0.437	0.508
Female	22	4		
Age (d)	11.30±3.57	38.29±7.42	12.251	0.001
Max classification (ear)				
I	34	4	6.580	0.010
II	26	14		
Malnormal site (n)				
Aures unitas	12	6	2.970	0.226
Auris sinistra	15	2		
Auris dextra	21	4		
External ear canal locking grading (ear)				
Level I	31	2	4.930	0.026
Level II	29	10		

表 5 EarWell 耳矫治器对新生儿耳廓畸形治疗预后不良的影响因素分析

Table 5 Analysis of the influence factors of EarWell ear appliance on poor prognosis in the treatment of neonatal auricle deformity

Factors	Parameter estimates	Standard error	Wald	<i>P</i>	OR	95% CI
Age	0.463	0.096	8.096	0.023	2.546	1.364~3.475
Max classification of auricular deformity	0.457	0.089	8.145	0.030	2.458	1.359~3.257
External auditory canal atresia classification	0.635	0.108	10.484	0.108	0.464	0.210~1.347
Appearance and ear length difference	0.847	0.304	13.274	0.124	0.747	0.314~1.249

明确;A 组患儿并发症发生率为 14.29%,B 组为 15.38%,C 组为 19.35%,组间对比,差异无统计学意义( $P>0.05$ )。由此证明,EarWell 耳矫治器的安全性较高,患儿并发症发生率较低,与陈敏建等<sup>[29]</sup>结果相符。陈敏建等结果显示,仅有 11.23%的患儿通过 EarWell 耳矫治器治疗出现的皮肤溃疡的并发症显现,并无严重并发症发生。这主要因为,EarWell 耳矫治器作为一种无创治疗手段,能够避免对新生儿手术治疗带来的创伤,同时能够及时进行早期干预,提升干预效果的同时,减少治疗周期,减少并发症的发生<sup>[27]</sup>。另外,耳廓矫治器的并发症发生与患儿后期护理、矫治器的安装以及体质肤质相关<sup>[28]</sup>。我院在对新生儿使用 EarWell 耳矫治器前对主治医师、护理人员进行了耳廓矫治器的培训,并对家长进行了耳廓矫治器家庭护理知识教育,从而降低了人为因素对患儿并发症的影响;预后良好组与预后不良组患儿性别、畸形部位对比无差异( $P>0.05$ ),预后良好组与预后不良组患儿年龄、耳廓畸形 Max 分型、外耳道闭锁分级以及容貌耳长差值对比差异显著( $P<0.05$ )。由此证明,年龄、耳廓畸形 Max 分型、外耳道闭锁分级以及容貌耳长

差值与 EarWell 耳矫治器治疗预后情况具有一定关系,与 Shahrin A 等<sup>[29]</sup>研究相似。Shahrin A 等研究发现,耳廓畸形的矫正治疗效果与患儿年龄和耳廓畸形严重程度具有一定相关性;logistic 回归分析结果显示,年龄、耳廓畸形 Max 分型为新生儿耳廓畸形治疗预后不良的独立影响因素( $P<0.05$ )。本研究结果与金加欣等<sup>[30]</sup>研究结果不符,金加欣等研究结果显示,仅有年龄为耳廓畸形矫治预后不良的影响因素。而本研究发现年龄、耳廓畸形 Max 分型均为耳廓畸形矫治预后不良的独立影响因素。这是因为,耳廓畸形 Max 分型越高代表患儿耳廓残缺程度越为严重,II 型耳廓严重发育不良,矫治难度较大的同时也很难达到应用的矫治效果。

综上所述,EarWell 耳矫治器对于新生儿耳廓畸形矫治效果显著,并发症发生率较低,且年龄越小矫治效果越好。年龄、耳廓畸形 Max 分型为耳廓畸形新生儿的预后不良的独立影响因素,临床上针对此类患儿需采取一定预防措施,预防预后不良现象的发生。

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