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REVIEW FACIAL SURGERY

Nonsurgical Treatment for Congenital Auricular Deformities: A Systematic Review and Meta-analysis

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Abstract

Background The effectiveness and safety of non-surgical correction for congenital auricular deformities (CADs) remain unclear owing to a lack of high-level evidence. This systematic review and meta-analysis aimed to estimate the overall success and complication rates of the non-surgical correction for CAD.

Methods We searched PubMed, Medline, and Cochrane Library for eligible studies. The pooled success and complication rates of non-surgical correction were estimated using a random effects model. Subgroup analyses were performed to compare the success rates between patients treated with splints and molding systems, between those younger and older than 6-weeks, and among those with different types of CADs.

Results The review yielded 14 studies. The pooled success rate of non-surgical treatment was 93% (95% CI: 88%-97%). The success rates with splints and commercialized molding systems were 94% and 92%, respectively. The success rate was higher if non-surgical correction was initiated before age 6 weeks (96% vs. 82%). Prominent ears showed a lower success rate (85%) than other types of CADs (all > 90%). The pooled complication rate was 18% (95% CI: 10%-29%). Complications, including skin wound, irritation, and rash, were mild and easily treatable.

Conclusion The non-surgical correction of CADs is highly effective and safe. Splints and molding systems offer similar effectiveness. Non-surgical correction is more beneficial if applied within 6 weeks of birth. Prominent ears have a lower, but still acceptable, success rate compared to other types of CAD. We recommend the early use of non-surgical correction to achieve favorable outcomes.

Level of Evidence III This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Congenital auricular deformities · Complication · Meta-analysis · Non-surgical correction

Introduction

CAD

Congenital auricular deformities (CADs) are characterized by an abnormal auricular appearance either with (i.e., malformation) or without (i.e., deformation) a structural defect. Auricular malformation indicates at least one absent chondrocutaneous component, whereas auricular deformation refers to an abnormal appearance with a complete chondrocutaneous component [1]. The incidence of CAD varies significantly by geography, with rates of 25% in the

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USA [2], 55.2% in Japan [3], and 20.9%−57.5% in China [4, 5].

Surgical Correction of CAD

CADs are traditionally corrected using surgical interventions around age 5 or 6 years [6]. However, surgery is associated with a high risk of complications, including cartilage exposure, infection, necrosis, scarring, and recurrence [7, 8]. In addition, such complications may compromise psychological development, leading to psychosocial problems such as social deficit, social withdrawal, and bullying [9]. Therefore, it is of great importance to offer a minimally invasive method for the early treatment of CAD.

Non-surgical Correction

Various non-surgical treatments have been described since the first such treatment was developed by Kuroumi et al. in 1982 [10]. Surgical tapes and splints made of different materials were used almost exclusively [11, 12] until Byrd et al. [13] introduced a commercialized ear correction system, EarWell (Becon Medical Ltd, Naperville, Illinois), for infant CAD in 2010. Regardless of the type of correction device, the underlying mechanism of non-surgical correction is that the neonatal auricular cartilage and skin are extremely pliable, and thus can be corrected by a continuous external force.

Gap of Knowledge

The reported success rates of non-surgical correction range from 71.6% to 100% [9, 14]. Differences in these rates may be attributable to different correction devices, different ages at initial treatment, and different type of CADs. In addition, several complications caused by the wearing of the correction device have been reported, but the incidence of such complications remains unclear. Although investigated in many observational studies, the effectiveness and safety of non-surgical correction remain elusive owing to a lack of high-level evidence (e.g., that obtained from randomized controlled trials). Thus, a systematic review and meta-analysis of existing observational studies would help elucidate the effectiveness and safety of non-surgical correction devices for CADs and further guide their clinical application.

Purpose and Aims

The purpose of this systematic review and meta-analysis was to estimate the overall success and complication rates of non-surgical correction devices for the treatment of CADs. The specific aims were to compare success rates 1) between patients treated with self-made splints and commercialized correction systems; 2) between those treated before and after age 6 weeks; and 3) among those treated for different types of CAD.

Method

Search Strategy

Two independent researchers (H.W. and Z.N.) searched PubMed, Medline, and Cochrane Library for studies published before October 1st, 2020. The following search term was used: ((((((noninvasive) OR nonsurgical) OR nonoperative) OR molding) OR reshaping) AND (((deformity OR anomalies) OR abnormalities) AND (((ear) OR auricular). All studies were downloaded to EndNote (version X9.2, Clarivate, Philadelphia, USA). The references cited in these studies were reviewed to identify additional eligible studies.

Studies included in the meta-analysis 1) described patients with CADs treated with non-surgical correction, such as splints, the EarWell system, or similar devices; 2) reported the success rate, or provided sufficient data for calculating the success rate of the correction types; 3) were published in English. Studies excluded in the meta-analysis 1) were case reports, letters, reviews, *in vitro* studies, animal experiments, technical reports, and abstracts; 2) did not report the data required for the meta-analysis; 3) had duplicated samples; 4) were not written in English; 5) were seriously flawed methodologically. G.L. and Y.L. independently reviewed the titles and abstracts of the studies to determine eligibility. Full texts of the included studies were obtained and reviewed.

Quality Assessment

The quality of the included studies was assessed by B.W. and J.Q. using the Quality Appraisal of Case Series Studies Checklist, a 20-item questionnaire [15]. We selected 10 relevant questions to evaluate the quality of the included studies. High-quality studies had positive answers to all 10 questions; moderate-quality had positive answers to 8 or more questions; and low-quality had positive answers to fewer than 8 questions [16]. Any disputes regarding study eligibility or quality were settled through discussion with an independent investigator (H.J.).

Data Extraction

Data extraction and cross-check were conducted by H.W. and Z.N. independently. The following data were

extracted: first author, publication year, country, study design, correction device (splint or system), patient sex, number of patients/ears, age at initial treatment, and treatment duration. The primary outcome was the success rate, as reported in the original studies. Several authors categorized the treatment outcomes as excellent, good, fair, or poor, whereas others categorized them as good, fair, or poor. We defined an excellent or good outcome as a successful one. If the success rate was not reported, we defined a successful outcome as a normal or nearly normal auricular appearance. The secondary outcome was the rate of complications caused by the wearing of the correction device, including skin lesion, pressure wound, ulceration, infection, skin irritation, maceration, excoriation, dermatitis, squeeze marker, rash, eczema, and allergic reaction.

Statistical Analysis

Statistical analysis was performed using Stata 16 (StataCorp LLC, College Station, Texas, USA). Interstudy heterogeneity was quantified using the I^2 statistic ($I^2 <$ 25%: low heterogeneity; 25% $\leq I^2 <$50%: moderate heterogeneity; 50% $\leq I^2 <$75%: high heterogeneity; $I^2 \geq$ 75%: substantial heterogeneity). If moderate or higher heterogeneity existed, a random effects model was used to pool the data and the potential source of heterogeneity was explored using sensitivity analysis by omitting one study at a time. Otherwise, a fixed-effect model was used. Subgroup analyses were performed to compare the success rates between patients treated with splints and molding systems, between patients treated before and after age 6 weeks, and among those with different type of CADs. Publication bias was assessed using the Egger test and a funnel plot; a $P <$ 0.05 for the Egger test and an asymmetrical funnel plot were considered to indicate possible bias. This study was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and checklist [17].

Results

Study Selection, Characteristics, and Qualitative Analysis

The flow chart of study selection is shown in Fig. 1. A total of 530 studies were initially identified. Of these, 164 were excluded due to duplicated retrieval. After the titles and abstracts were screened, 334 irrelevant articles were excluded. After the full texts of the remaining 32 studies were reviewed, a total of 14 studies (8 retrospective and 6 prospective) of 1,727 ears were finally included in the meta-analysis (Table 1). Splints were used in 9 studies (most of which were published before the molding system was invented), whereas molding systems were used in 5 recent studies. There were 8 moderate-quality studies and 6 low-quality studies (Fig. 2).

Success Rate

Successful outcomes were reported for 1,530 out of 1,727 (88.6%) ears. The pooled success rate was 93% (95% confidence interval [CI]: 88%-97%) with substantial heterogeneity (Fig. 3a). Sensitivity analysis did not detect the source of heterogeneity.

Splints vs. Systems

Successful outcomes were reported for 555 of 652 (85.1%) ears treated with splints and 975 of 1075 (90.7%) ears treated with molding systems, respectively. The pooled success rate was 94% (95% CI: 85%-100%) for splints and 92% (95% CI: 87%-96%) for moldings with substantial heterogeneity (Fig. 3b). The success rates between patients treated with splints and those treated with moldings were not significantly different.

Before vs. After Age 6 Weeks

Successful outcomes were reported for 792 of 839 (94.4%) ears and 209 of 282 (74.1%) ears treated before and after age 6 weeks, respectively. The pooled success rate was 96% (95% CI: 93%-98%) for the former and 82% (95% CI: 58%-98%) for the latter with substantial heterogeneity (Fig. 3c). the considerable difference in success rates between the two subgroups demonstrated that non-surgical correction was more beneficial if applied earlier, particularly within 6 weeks after birth.

Different Types of CAD

Successful outcomes were reported for 167 of 204 (81.9%) prominent ears, 141 of 153 (92.2%) Stahl's ears, 116 of 128 (90.6%) lop ears, 254 of 286 (88.8%) cryptotia cases, 173 of 196 (88.3%) ears with helical rim abnormalities, and 43 of 52 (82.7%) constricted ears. The pooled success rate was 85% (95% CI: 71%-96%) for prominent ears, 99% (95% CI: 90%-100%) for Stahl's ears, 97% (95% CI: 81%-100%) for lop ears, 91% (95% CI: 65%-100%) for cryptotia, 91% (95% CI: 74%-100%) for ears with helical abnormalities, and 93% (95% CI: 58%-100%) for constricted ears (Fig. 3d). Intervention for prominent ears showed a substantially lower success rate than those for other types of CAD did.

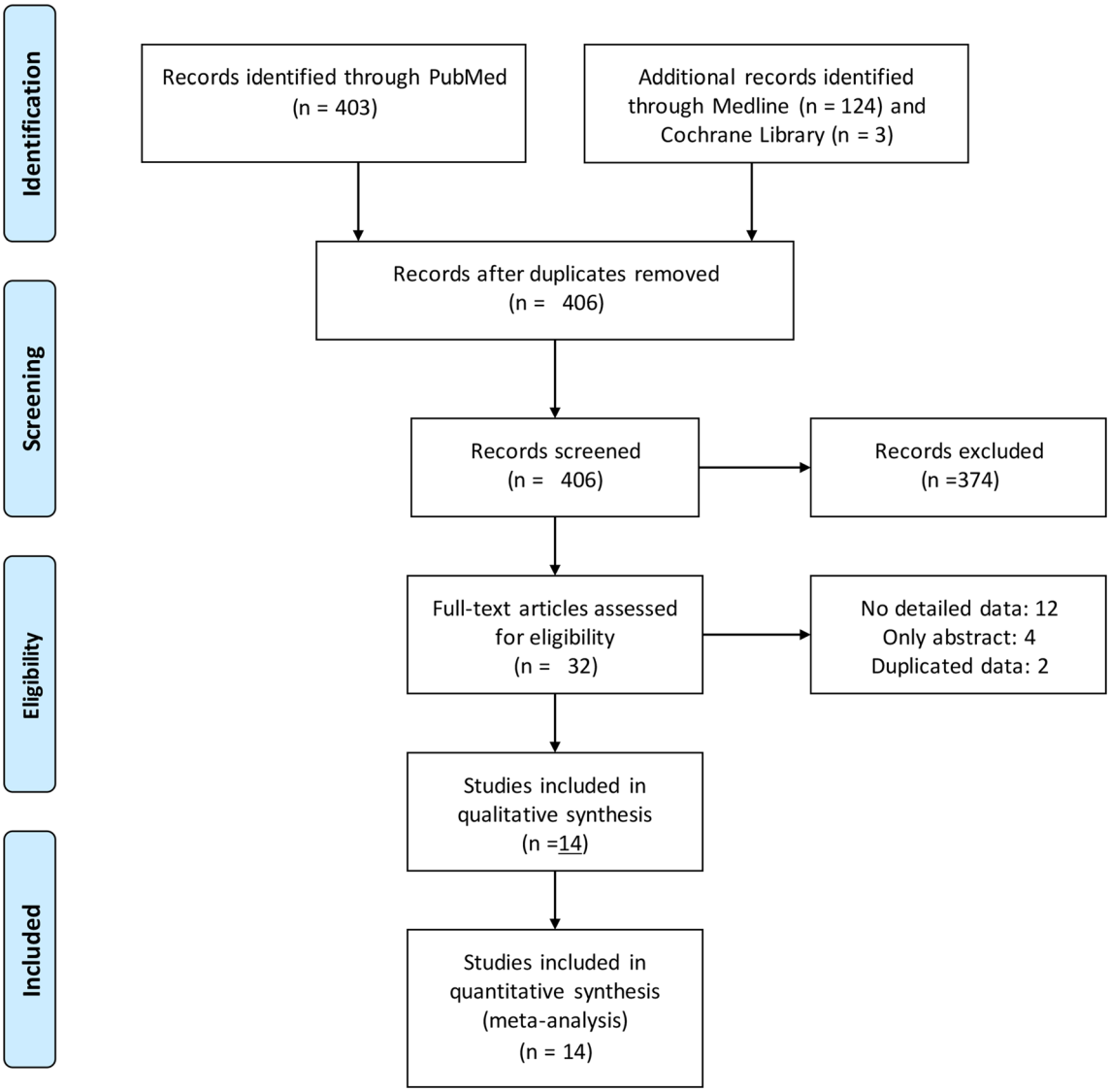

Fig. 1 Flow chart of study selection

Complication Rate

Four studies reported complications in 92 of 571 (16.1%) ears. The pooled complication rate was 18% (95% CI: 10%-29%) with substantial heterogeneity (Fig. 4).

Publication Bias

The basically symmetrical funnel plot (Fig. 5) and the results of the Egger test (t= 1.25, P= 0.23)indicated no evidence of publications bias.

Discussion

Major Findings

The results of the meta-analysis confirm that the non-surgical correction of CADs is highly effective and safe. Splints and molding systems offer similar effectiveness. Non-surgical correction is more beneficial if applied within 6 weeks of birth. Prominent ears have a lower, but still acceptable, success rate compared to other types of CAD.

Success Rate

Consistent with previous studies, the present study showed that the non-surgical correction has a high pooled success rate, even compared with that of otoplasty, which ranges

Table 1 Characteristics of included literature

No. study	First Author	Year	Country	Study Design	Correction Devices	Gender (Boys)	Number of Patients	Number of Ears	Initial Age	Treatment Duration (mean)
1	Tan et al.	1997	USA	Prospective	Splint	10	19	32	Mean=16.9 d	63.7 d
2	Sorribes et al.	2002	Denmark	Prospective	Splint	23	44	56	2 w-5.5 y	165 d
3	Ullmann et al.	2001	Israel	Prospective	Splint	30	52	92	< 10 d	47.6 d
4	Yotsuyanagi et al.	2004	Japan	Retrospective	Splint	24	216	275	0-1m: *n*=46; 1-3 m: *n*=57; 3-6m: *n*=42; 6 m-1 y: *n*=37; 1-3 y: *n*=43; 3-6 y: *n*=22; 6-9 y: *n*=13; 9 y: *n*=15	NA
5	Smith et al.	2005	Canada	Retrospective	Splint	NA	NA	69	< 10 d	NA
6	Schonauer et al.	2009	Italy	Retrospective	Splint	NA	36	56	1-2 d	NA
7	Leonardi et al.	2012	Italy	Retrospective	Splint	8	12	22	2-42 d	NA
8	Petersson et al.	2012	USA	Prospective	Splint	4	9	17	Mean= 1.4 d	24.9 d
9	Woo et al.	2016	Korea	Retrospective	System	13	18	28	Mean= 22.6 d	32.7 d
10	Chang et al.	2017	USA	Retrospective	Splint	NA	24	33	Mean= 31.2 d	27 d
11	Daniali et al.	2017	USA	Retrospective	System	NA	111	303	Mean= 12.5 d	37 d
12	Chan et al.	2019	Singapore	Prospective	System	37	45	71	Mean= 15.7 d	28.7 d
13	Zhang et al.	2019	China	Retrospective	System	NA	105	141	< 6 w: *n*=76 > 6 w: *n*=65	34.2 d
14	Xiong et al.	2020	China	Prospective	System	NA	462	532	12-112 d	NA

from 92.9 to 94.6% [18]. However, non-surgical treatment cannot completely replace otoplasty and other surgical interventions; surgery is still required if the ear does not respond well to the non-surgical correction. The outcome of non-surgical correction is affected by many factors, including the type of correction device, age at initial treatment, treatment duration, and type of CAD.

Splints vs. Systems

Noninvasive correction devices for CADs fall into three major categories: 1) medical tapes and bandages[19]; 2) splints made of wires, Reston foam, Velfoam, and dental and thermoplastic materials [20–22]; 3) correction molding systems (e.g., EarWell) made of non-irritating, non-allergic, non-toxic polyurethane thermoplastic elastomer. Yotsuyanagi et al.[14] used thermoplastic splints to treat CADs and reported an effective rate of 82% for cryptotia but only 50% for lop ears and prominent ears. Recent studies suggest that correction systems are more effective for all types of auricular deformations. However, our meta-analysis found no significant difference in success rates between splints and systems. Because correction systems are more standardized and ergonomic, and have more user-friendly designs, thus may be associated with less complications [23, 24].

Age at Initial Treatment

Patient age at initial non-surgical treatment is a determinant of successful outcomes [13, 25, 26]. Previous studies have shown that earlier initial treatment is associated with better outcomes and shorter treatment duration, but the optimal initial treatment remains controversial. Byrd et al.[13] found that the success rate of EarWell was higher than 90% if started within 1 week after birth but less than

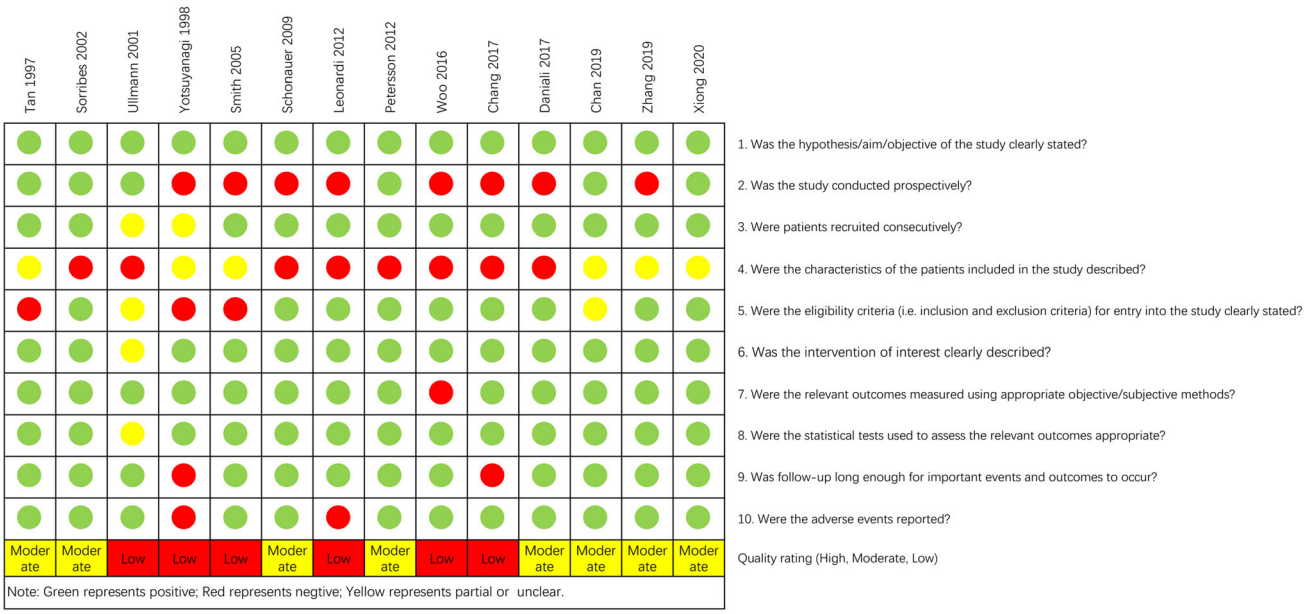

Fig. 2 Quality assessment of the included studies

50% if started after 3 weeks. Yotsuyanagi et al. [14] reported that non-surgical treatment had success rates of 91.3% and 80.7% if started within 4 weeks and at 4-12 weeks, respectively. van Wijk et al. 2012 [27] reported that non-surgical treatment started within 6 weeks, at 6-12 weeks, and beyond 13 weeks had success rates of 78.8%, 57.6%, or 46.7%, respectively. Similarly, Zhang et al. [28] demonstrated that treatment started before 6 weeks had a significantly higher success rate than that started after 6 weeks. In addition to higher success rate, early treatment is also associated with lower treatment duration. The treatment duration is less than 2 weeks for 1-week-old infants, 1 month for 1- to 6-week-old infants, and may be more than 2 months for infants older than 6 weeks. Doft et al. [29] started non-surgical correction on 158 ears within 2 weeks after birth and reported a success rate of 96% after 2 weeks of treatment. In contrast, Mohammadi et al. [25] noted a success rate of 57% after 13 weeks of treatment for 21 infants whose mean age was 7 weeks.

Successful outcomes have been reported for patients who started non-surgical treatment late, however. Muraoka et al. [19] reported good outcomes in a 2-year-old boy with Stahl's ears after 3 months of tape fixation and in a 3-year-old girl with cryptotia after 1 year of non-surgical treatment. Sorribes and Tos [21] observed good outcomes of prominent ears in patients as old as 5.5 years. Yotsuyanagi et al. [14] noted good outcomes of non-surgical correction in patients as old as 16 years. They further reported a successful outcome in a 32-year-old woman with cryptotia after 3 weeks of treatment with a splint and suggested that the cartilaginous elasticity, rather than the patient's age, was the determinant of treatment outcome [14]. On the basis of this theory, Leclere et al. [30] heated the auricular cartilage of an adult prominent ear with a 1064-nm neodymium-doped yttrium aluminum garnet laser and provided molding correction. Their results indicated that the laser treatment assisted cartilage reshaping by achieving stress relaxation without damaging to the chondrocytes or auricular cartilage matrix.

In accordance with van Wijk et al. [27] and Zhang et al. [28], we found a substantially higher success rate for patients who started non-surgical correction before 6 weeks of age. This is because the pliability of the auricle is determined by the level of hyaluronic acid in the auricular cartilage, which is positively related to the remaining maternal estrogen in the neonatal circulation. The estrogen level peaks on postnatal day 3 and decreases to the normal level by week 6, resulting in an optimal time frame when the auricular cartilage is pliable and can be molded into a proper shape [3, 5]. Given that 30% of auricular deformations spontaneously improve within 2 weeks after birth, Byrd et al. [13] recommended a revisit on day 7 and non-surgical correction to patients without improvement. For patients with partial improvement, another revisit on day 17 would determine whether non-surgical treatment is required. In contrast, several authors [3] advocated an early intervention before postnatal day 3 without further observation, particularly for those with prominent ears or a family history of other CADs.

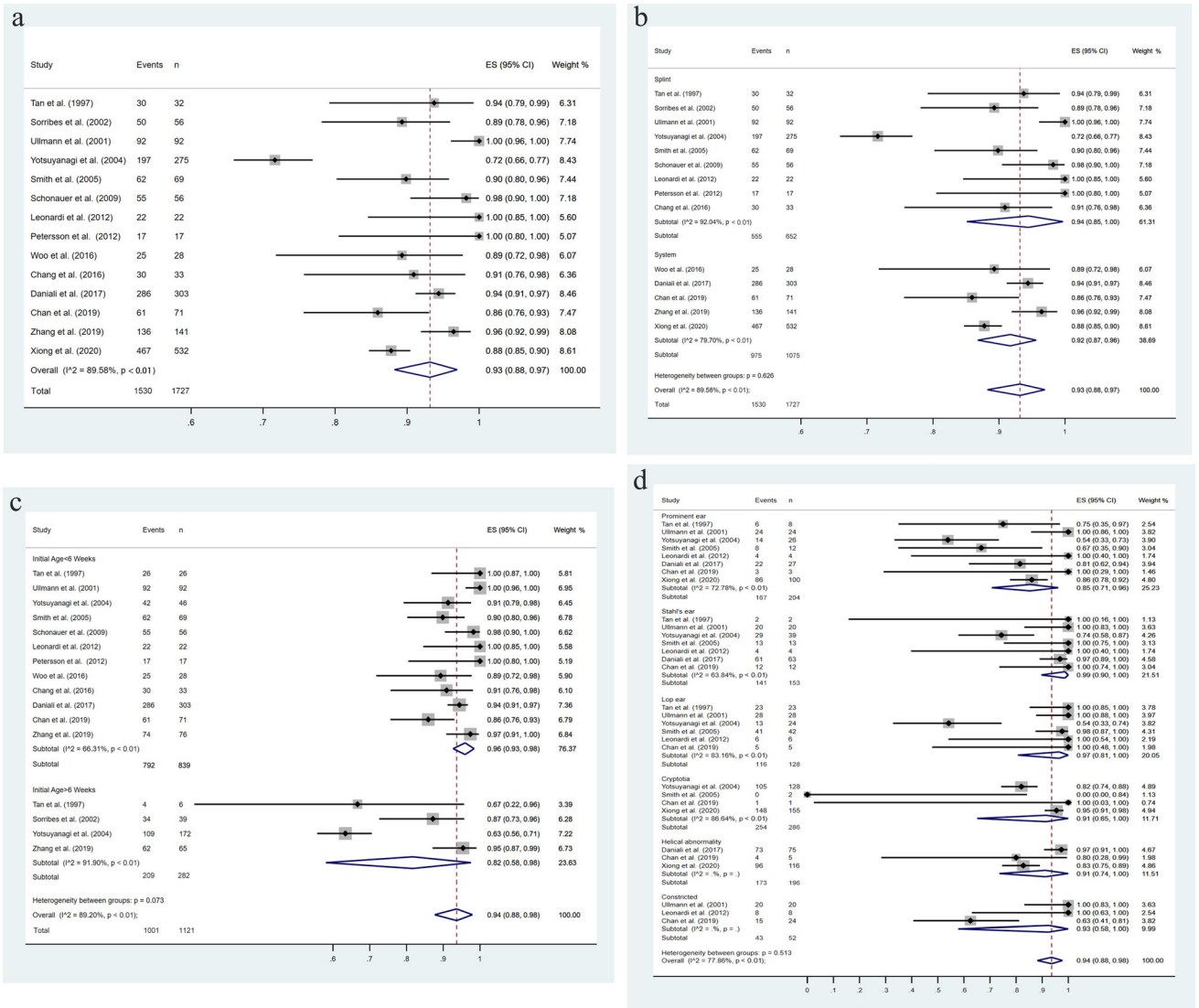

Fig. 3 **a** Forest plot of the overall success rate. **b** Success rates for patients treated with splints and molding systems. **c** Success rates for patients treated before and after 6 weeks of age. **d** Success rates for patients with different types of congenital auricular deformities.

Prominent Ears are Difficult to Correct

The 7 major types of CADs are lop ears, constricted ears, prominent ears, cryptotia, Stahl's ears, helical rim abnormalities, and conchal crus. Owing to a lack of data, we did not estimate success and complication rates for patients with conchal crus in the present study. Cryptotia and Stahl's ears can be corrected nonsurgically at any age by lengthening the shortened skin and superior auricular muscles, but a late start may prolong the treatment duration [31, 32]. However, non-surgical correction has a lower success rate and higher recurrence rate for lop ears and prominent ears, particularly if started after the optimal time frame. Zhong et al. [33] used EarWell on 28 infants whose median age was 6 weeks (range: 4-14 weeks) and noted an immediate success rate of 97.2%, but, owing to a high recurrence rate in patients with level-II constricted ears and prominent ears, a success rate of 83.3% at 6 months. Tao et al. [34] used EarWell on 76 infants older than 3 months and reported success rates of 87.5% at the end of treatment and 68.1% at 3-month follow-up. They concluded that non-surgical treatment performed after 6 weeks was less effective for prominent ears and lop ears. Similarly, Sorribes and Tos [21] and Daliali et al. [1] reported fair to good outcomes in about 80% of patients with prominent ears. Yotsuyanagi et al. [14]. noted a considerably low success rate of 53.8% in patients with prominent ears. In accordance with these studies, we found that prominent ears had the lowest success rate (85%) compared to other types of CADs (all > 90%). These unsatisfactory outcomes may be caused by the following reasons. First, it is difficult to diagnose prominent ears in newborns. The golden time

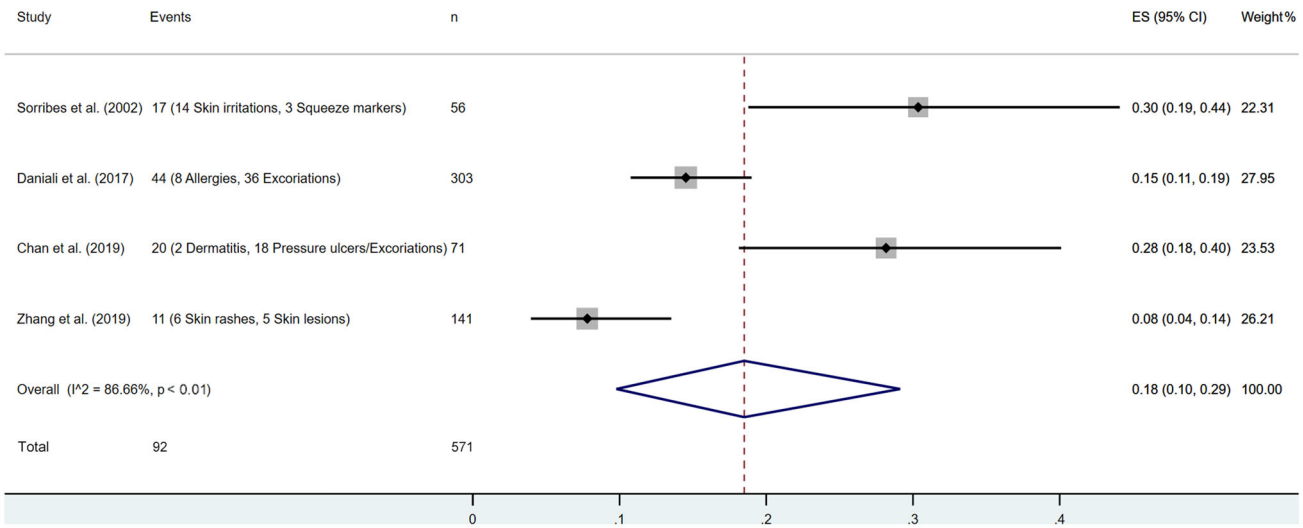

Fig. 4 Forest plot of the overall complication rate.

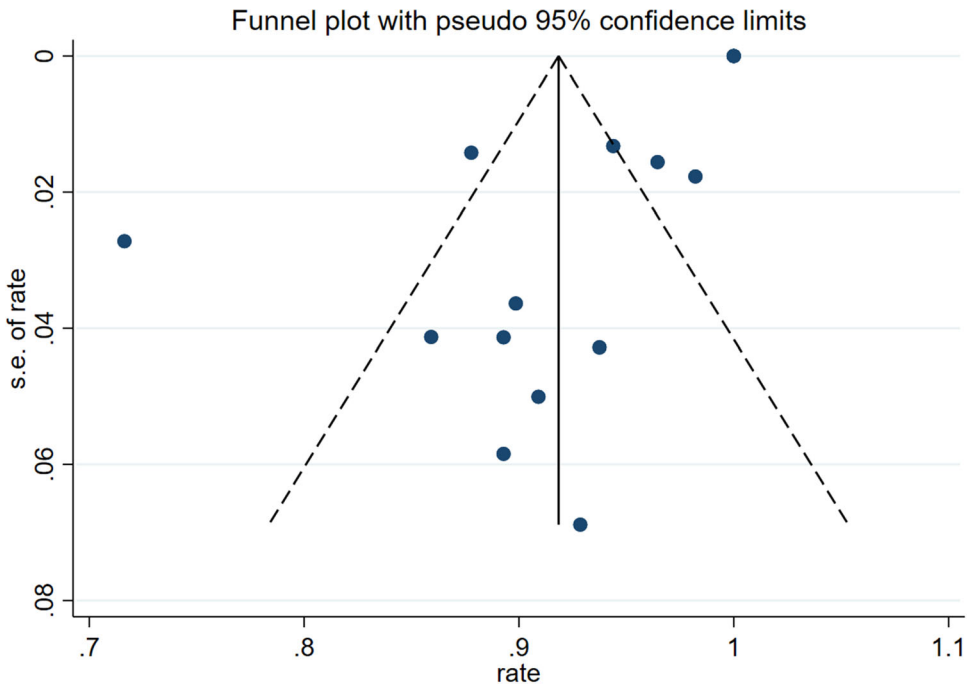

Fig. 5 Funnel plot for publication bias.

for molding is always missed when prominent ears are obvious. Second, prominent ears involve overlong posterior auricular muscles, which are difficult to correct nonsurgically. Third, deformities of the conchal bowl are largely ignored and remain a primary source of prominent overgrowth. Any method of treatment that does not apply anterior (downward directed) forces to the conchal bowl will be less ineffective. Despite these shortcomings, nonsurgical correction is still beneficial as a pre- and/or postoperative step to minimize the risk of complications and recurrence in patients with prominent ears and other severe CADs.

Complication Rate

We found that complications related to the wearing of correction devices are mild. According to previous studies, such complications are easily treatable. Sorribes et al. [21] noted that skin irritations disappeared after suspending treatment, which did not affect the treatment outcome. Doft et al. [29] found that skin ulceration occurred in 3% of

infants and improved after the application of bacitracin. Chan et al. [35], in a study of patients in Singapore, noted that 25.4% of patients developed pressure wounds and attributed the high risk of complications to the humid climate. The risk of complications may be higher among patients who are older at initial treatment because the auricular cartilage becomes harder and larger as infants age. In the present study, regardless of the type, complications always resolved within several days after treatment suspension and the local administration of povidone iodine or a topical antibiotic such as mupirocin or erythromycin. The treatment could be restarted several weeks later to allow the wound maturation. Even so, close follow-up is necessary because complications may be the reason for therapy cessation [27].

Limitations

This study had several limitations. First, specific parts of the ear may respond worse to the non-surgical treatment than others due to a different composition of cartilage, muscle, and skin. For example, conchal deformities are the most resistant to molding, thus molding must be started very early for successful outcome. However, most studies ignored this fact which may compromise the pooled results. Second, treatment duration plays a critical role in the outcome of non-surgical correction, but most studies included in the meta-analysis did not report this information. Third, owing to a lack of data, we were unable to perform meta-regression to estimate the association between the success rate and age at initial treatment or other factors. Fourth, although we detected substantial interstudy heterogeneity, we did not identify the source of this heterogeneity through sensitivity analysis. Three major reasons may account for the heterogeneity. First, many studies did not reported the treatment and follow-up duration, which significantly influenced the outcome assessment. Second, sample size of each study significantly varied, ranging from 9 patients (17 ears) to 462 patients (532 ears). Third, the quality of meta-analysis relies on the quality of included studies. Among the 14 included studies, 8 were of moderate- and 6 were of low-quality. This was expectable because all were single-centered observational studies and most of them were retrospective in design. However, meta-analysis of single-arm observational studies is still a useful method to provide higher level of evidence when controlled trials are unavailable or unfeasible, especially on vulnerable target population, e.g., infants. Future randomized controlled trial with adequate sample size, objective evaluation of the outcomes, and long follow-up may better elucidate these issues. Despite these limitations, this is the first meta-analysis to assess the effectiveness and safety of the non-surgical correction of CAD. This up-to-date evidence may help obstetricians, pediatricians, otolaryngologists, and plastic surgeons optimize the application of non-surgical correction and minimize complications.

Conclusion

We found that non-surgical correction is highly effective and safe in treating CAD. Self-made splints and commercialized molding systems offer similar effectiveness. Non-surgical correction is more beneficial if applied within 6 weeks after birth. Prominent ears show a substantially lower, but still acceptable, success rate compared to other types of CAD. Based on these findings, we recommend the early use of correction systems to achieve favorable outcomes. The low response rate of prominent ears should be discussed with parents in advance.

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Declarations

Conflict of interest All authors state that there is no conflict of interest.Informed ConsentInformed consent is not required for this type of study.Human and Animal RightsThis article does not contain any studies with human participants or animals performed by any of the authors.

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