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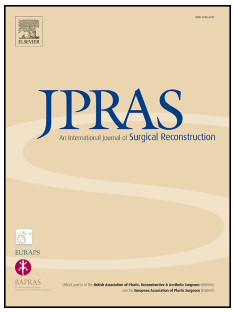

Complications after prominent ear correction – A systematic review of the literature

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COMPLICATIONS AFTER PROMINENT EAR CORRECTION – A SYSTEMATIC REVIEW OF THE LITERATURE.

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KEYWORDS: complications; haematoma; otoplasty; pinnaplasty; prominent ears; bat ears.

ABSTRACT

Background: There is great diversity in reported post-operative outcomes for otoplasty, with the incidence of haematoma or infection ranging from 0 percent to 15.6 percent and 0 percent to 10 percent respectively. With such variability it is difficult to determine an overall "average" incidence of common post-operative complications.

Methods: A systematic review of the most relevant medical databases was conducted for English language studies published between January 1, 2000 and December 31, 2015. Using the data set, pooled estimates for the incidence of the primary and secondary outcomes were calculated for all included studies. The primary outcome was haematoma and/or bleeding incidence and the secondary outcomes included infection, skin/wound healing problems, suture-related problems, scarring, pain and itching and revision surgeries/recurrence. Comparable sub-group analysis of studies was also carried out using calculated pooled proportions.

Results: After screening, 28 articles involving 3493 patients were included in the study. Pooled proportions revealed haematoma and/or bleeding incidence was 2.5 percent (95 percent CI: 1.4 – 3.8 percent); infection 0.8 percent (95 percent CI: 0.4 – 1.3 percent); skin/wound healing problems 3 percent (95 percent CI: 1.4 – 5.1 percent); suture-related problems 1.8 percent (95 percent CI: 0.8 – 3.2 percent); scarring 1.6 percent (95 percent CI: 0.8 – 2.6 percent); pain and itching 13 percent (95 percent CI: 5.4 – 23.1 percent) and revision surgeries/recurrence 5 percent (95 percent CI: 2.9 – 7.7 percent).

Conclusions: By pooling proportions of reported complications, the results of this study could be useful in personal audit of practice and will also be a point of reference for comparing novel surgical techniques in the future.

INTRODUCTION

Prominent ears or prominauris is common and about 5 percent of the general population have this condition.[1,2] It mostly results from either conchal hypertrophy and/or poor development of the antihelical fold, leading to the protrusion of the auricle.[1,3,4] Though posing no physiological handicap, children who suffer from this condition are can be faced by ridicule from their peers in social situations prompting them to seek surgical treatment.[1,5,6] To date, various surgical techniques are used to treat prominent ears on a heterogeneous patient population.[7,8]

Moreover, otoplasty is not unique with regards to its numerous surgical techniques and diverse patient population.[9] Other surgical treatments such as hypospadias repair or cleft palate reconstruction also show this varied treatment methodology and patient cohort.[9] This will not only lead to different rates of reported post-operative complications but to slightly different complication profiles in the individual studies.[9] For example, the incidences of common post-otoplasty complications such as haematoma or infection range from 0 percent to 15.6 percent and 0 percent to 10 percent respectively.[10,11,12] These two complications along with scarring and post-operative pain are important factors that could impact a patient's surgical outcome. Patients who develop hypertrophic scarring could face further aesthetic difficulties following surgery, or a neglected haematoma could lead to other problems such as tissue necrosis and auricular deformity.[13] Having an "average" pooled incidence of common complications will not only benefit the surgeons and medical staff, but will also allow patients to give more informed consent prior to the operation.

The objective of this study is not to determine the ideal surgical methodology or to critique the work of the individual surgeons; but to provide a mean incidence of post-operative complications via pooled proportion analysis.[9] By reporting an "average" incidence of complications this study can help produce outcome standards and aid personal audit.

Simultaneously the information contained in this review could prompt medical staff to ensure good quality care is delivered and any deficiencies in the surgical and postsurgical process to be addressed.

MATERIALS AND METHODS

Data sources

A systematic review of the literature was carried out across four electronic databases: Cochrane Central Register of Controlled Trials, PubMed, EMBASE and CINAHL. The following search terms were used: (pinnaplasty OR otoplasty OR "prominent ears" OR "bat ears") AND (complications). Publications were limited to English language and within the date range of January 1, 2000, to December 31, 2015.

Study selection

Eligibility of articles was determined using the population, intervention, comparator, outcome and study design approach (PICOS).[14] Articles were reviewed independently by two researchers (SSS/SM) with adherence to the inclusion and exclusion criteria summarised in Table 1. It was decided that the primary outcome measure should be the reporting of the presence or absence of haematoma and/or bleeding, as this was the most widely reported complication throughout the literature. Hence if an article did not explicitly mention that they recorded haematoma and/or bleeding, regardless of incidence, it was excluded. If an article only included a sub-group of patients who met the inclusion criteria, but could successfully be extracted from the final cohort, it was included in the review (e.g. patients who only received a pinnaplasty procedure extracted from a mixed cohort of patients, some of whom also had concurrent procedures). Furthermore, articles were only included if complication rates were measured in terms of patient numbers rather than number of ears; however if this could be calculated based on reported percentages, the article was included. If this could not be done in a mixed cohort, data was viewed as non-extractable and subsequently excluded.

Two levels of screening were undertaken in order to select the final articles. The first level screened the title and abstract, and the second level involved reading the full-text article. Only once an article passed both levels of screening and agreed on by all the authors, was it deemed applicable to this review. Our process of analysing the studies identified throughout the literature search followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) criteria.[14]

Assessment of methodological quality

All randomised clinical trials (RCTs) included in this review were assessed against the Consolidated Standards of Reporting Trials (CONSORT)[15] and methodological quality of were assessed using the Detsky score.[16] For non-randomised trials, the Methodological Index for Non-Randomised Studies (MINORS) was used.[17] For each study, a Detsky score was calculated from a maximum of 20, or a MINORS score was calculated from a maximum of 24 for comparative studies and 16 for non-comparative studies. If a study achieved at least 75 percent of the maximum Detsky or MINORS score, it was deemed to be of high quality.[18,19]

Data extraction and statistical analysis

Data was recorded using Microsoft Excel (Redmond, WA, USA) and Table 1 summarises the data extracted. Further complications such as under-correction, over-correction, residual deformity, excess skin and asymmetry were not evaluated in this review as they were open to subjective assessment and recording. A kappa score was calculated between both reviewers with regards to the final list of included articles in order to provide a statistical approximation of agreement. Subsequently, multiple pooled proportion analysis was undertaken for the primary outcome, each secondary outcome (infection, skin/wound healing problems, suture-

related problems, scarring, pain and itching and revision surgeries/recurrence) and also to compare outcomes against continental origin and surgical technique.

To facilitate analysis, complications were grouped as follows: 1) haematoma and/or bleeding (includes immediate post-operative bleeding and post-operative haematoma); 2) infection (includes clinical diagnosis of infection, infections requiring antibiotics, epidermolysis and chondritis); 3) skin/wound healing problems (includes anterior skin necrosis, pressure necrosis, delayed wound healing, and granuloma formation); 4) suture-related problems (extrusion, stitch granuloma formation, inflammatory reaction to absorbable suture, suture failure and recurrence of prominence in suture-based procedures); 5) scarring (including hypertrophic and keloid scars); 6) pain and itching (including hypersensitivity and cold sensitivity); and 7) revision surgeries/recurrence (including those requiring and not requiring surgical correction). Aesthetic outcomes (unnatural appearance, "Spock" ear, telephone ear, under correction, and over correction) were not analysed due to the lack of objectivity and inconsistency in assessment.

Prior to the analysis, we tested the significance of heterogeneity between studies using the Cochran Q test.[20] These tests indicated the presence of heterogeneity, hence random effects models were used throughout. All statistical models were produced and presented using Stats Direct (StatsDirect Ltd, Cheshire, UK). In order to make comparisons between subgroups, the pooled values, and confidence intervals, from the models were transformed using the Freeman-Tukey double arcsine method.[21,22] The resulting values were converted into means and standard errors, which were compared by t-test. Statistical significance was considered at the threshold value of $p < 0.05$.

RESULTS

Study selection and assessment of methodological quality

244 articles were identified from the literature search, of which 144 moved onto the first level of screening once duplicates were removed. Upon application of inclusion and exclusion criteria, 91 proceeded onto the full-text eligibility screening. After these 91 articles were thoroughly read, it was decided that only 28 were eligible for inclusion in the final data extraction for this review (kappa = 0.86); Fig. 1).[10-12,23-47] These consisted of two RCTs and 26 non-randomised studies: 22 of which were non-comparative and four comparative studies. The mean Detsky score for RCTs was 14.5, with one study meeting the threshold of a high quality study. For non-comparative studies the mean MINORS score was 11.7, ten of which were deemed high quality; and the mean score for comparative studies was 17, with three studies of high quality (Appendix 1).

Data extraction

A total of 3493 patients were included from the final 28 articles selected for this review. In terms of continent/country of origin, ten studies were from the U.K (*n* = 784 patients), eight were from continental Europe (*n* = 896 patients), five were from the Americas (*n* = 1431 patients) and five from Asia (*n* = 382 patients). Despite limiting the date of publication to January 1, 2000 onwards, some retrospective cohorts reported cases from as far back as 1992.[39] Furthermore, the age at which patients underwent surgery varied greatly, from three years[34] to 72 years.[37] This information was presented in a multitude of ways across 25 articles. Some displayed this as an age range and others as a mean or median age, thus

rendering it impossible to produce any effective analysis or robust conclusions upon which the optimal age for pinnaplasty could be deduced.

The design of studies generally presented cases in one of the following three formats: (a) a cohort study consisting of a single technique; (b) a non-comparative study consisting of two or more techniques; or (c) a comparative study consisting of two or more techniques. Of those which were comparative, some used prospective data collection which ran in conjunction throughout the study, whilst others used retrospective data comparing previous cohorts. The majority of studies were non-randomised and non-comparative. An array of different surgical techniques and protocols were described, highlighting the lack of homogeneous management across the included patient population. The number of surgeons involved in a study ranged from one to five, with the modal figure being one. Surgical techniques were broadly grouped into three categories: (a) suture based (e.g. scapho-conchal, concha-mastoid sutures etc.); (b) cartilage manipulation (e.g. anterior scoring); or (c) a combination of both suture based techniques and cartilage manipulation techniques. Three articles (n = 326 patients) reported solely suture based techniques and three articles (n = 1021 patients) reported solely cartilage manipulation techniques. The remaining 22 articles consisted of patients who either underwent a combination procedure, or patients of the same cohort underwent suture based and some non-suture based techniques, with unextractable complications rates to make a comparison between the two.

Complications were variably described and presented (Appendix 1). The primary outcome, haematoma and/or bleeding, was the most widely reported (in 28 articles; n = 3493 patients); followed by the secondary outcomes: revision surgeries/recurrence (in 25 articles; n = 3229 patients); infection (in 23 articles; n = 3171 patients); skin/wound healing problems (in 20 articles; n = 2762 patients); scarring (in 19 articles; n = 2681 patients); suture-related problems (in 16 articles; n = 1669 patients) and pain and itching (in nine articles; n = 736

patients). The crude haematoma and/or bleeding incidence ranged from 0 percent to 15.6 percent; revision surgeries/recurrence from 0 percent to 30.8 percent; infection from 0 percent to 10 percent; skin/wound healing problems from 0 percent to 14.7 percent; scarring from 0 percent to 8.3 percent; suture-related problems from 0 percent to 11.9 percent and pain and itching from 1.2 percent to 60 percent. Follow-up was reported either as a mean, median, range, or any combination of the three. To ensure consistency and standardisation, the minimum follow-up was used for data extraction. This ranged from ten days to 24 months, with a median of nine months calculated across 19 articles.

Data synthesis and analysis

Using the dataset, pooled estimates of the proportions of our primary outcome and secondary outcomes could be calculated. Thus meaning the overall incidence of haematoma and/or bleeding was 2.5 percent (95 percent CI: 1.4 - 3.8 percent; Fig. 2); revision surgeries/recurrence 5.0 percent (95 percent CI: 2.9 – 7.7 percent); infection 0.8 percent (95 percent CI: 0.4 – 1.3 percent); skin/wound healing problems 3.0 percent (95 percent CI: 1.4 – 5.1 percent); scarring 1.6 percent (95 percent CI: 0.8 – 2.6 percent); suture-related problems 1.8 percent (95 percent CI: 0.8 – 3.2 percent) and pain and itching 13.0 percent (95 percent CI: 5.4 – 23.1 percent).

Further datasets could also be established based upon the continent/country of origin. From continental European studies, the pooled proportion of haematoma and/or bleeding was 3.1 percent (95 percent CI: 0.8 – 6.9 percent); from Asian studies it was 2.4 percent (95 percent CI: 0.2 – 7.1 percent); from American studies it was 2.4 percent (95 percent CI: 0.6 – 5.5 percent) and from British studies it was 1.9 percent (95 percent CI: 0.7 – 3.6 percent). Africa and Australasia yielded no studies which fitted our inclusion criteria. There was no statistically significant difference in the incidence of haematoma and/or bleeding between

these geographical regions (Fig. 3). Likewise, pooled proportions calculated from European, Asian, American and British studies for revision surgeries/recurrence revealed no statistically significant difference in incidence based on geographical region of origin. These were 4.4 percent, 2.0 percent, 6.2 percent and 8.0 percent respectively. However, British studies had a statistically significant higher rate of infection, 2.7 percent (95 percent CI: 1.1 – 5.0 percent), compared with European studies, 0.2 percent (95 percent CI: 0 – 0.6 percent); Asian studies, 0.3 percent (95 percent CI: 0 – 1.1 percent) and American studies, 0.5 percent (95 percent CI: 0.2 – 0.9 percent), ($p < 0.01$). Also, British studies had a statically significant higher rate of skin/wound healing problems, 4.4 percent (95 percent CI: 1.6 – 8.5 percent), compared to Asian studies, 1.0 percent (95 percent CI: 0.2 – 2.3 percent) and American studies, 1.0 percent (95 percent CI: 0.7 – 7.7 percent), but not European studies, 3.6 percent (95 percent CI: 0.6 – 9.2 percent), ($p < 0.01$).

When comparing surgical methodology, suture-based techniques had a statistically significant higher rate of revision surgeries/recurrence, 13.6 percent (95 percent CI: 7.8 – 20.7 percent), than cartilage manipulation techniques, 8.5 percent (95 percent CI: 0.1 – 28.6 percent), ($p < 0.0001$). Cartilage manipulation techniques had a higher rate of skin/wound healing problems, 4.3 percent (95 percent CI: 0 – 17.8 percent) compared with 0.6 percent (95 percent CI: 0 – 1.9 percent) for suture-based methods; however this was not statistically significant. There was also no statistically significant difference in the incidence of haematoma and/or bleeding between the two groups. The incidence of suture-related problems (e.g. extrusion) for suture-based techniques was 2.8 percent (95 percent CI: 0.6 – 6.6 percent).

DISCUSSION

The great variation in otoplasty techniques and their patient cohorts results in differing post-operative outcomes both in terms of complications and recurrence rates. This literature review aims to address this problem, by pooling the outcome data and providing average incidence rates of common post-operative complications, regardless of the type of prominauris and surgical methodology. The inclusion of all patients undergoing otoplasty (primary or secondary) reflects the broad applicability of this review along with its inherent use in auditing the work of other surgeons.

The majority of the included studies were of high methodological quality in terms of reporting. The use of strict inclusion/exclusion criteria, search terms and two independent researchers who achieved high levels of interpersonal agreement allowed for a robust method of standardisation to select the most relevant and reliable medical data for common post-otoplasty outcome measurements. Many studies reported outcomes in terms of patient ears rather than patient numbers and thus did not meet the criteria for data extraction mentioned in Table 1 and subsequently excluded. Studies that did not explicitly acknowledge the presence or absence of haematoma and/or bleeding were also excluded as it required an ambiguous assumption of whether the study did not have any haematoma and/or bleeding in their respective patients or whether the authors forgot to record this complication. This opens the possibility of voluntarily neglecting valid surgical data which could lead to an aspect of selection bias in our results. The stringent use of only English language studies deprives us of

additional information from other parts of the world, potentially limiting the applicability of our work in non-English speaking nations.

All three authors agreed to use January 1, 2000 as an arbitrary cut off point and only selected articles published after this date in an attempt to capture contemporary information. Despite the majority of patients undergoing surgery in this timeframe, a number of patients underwent surgery up to eight years prior to this date,[39] potentially reflecting that the data may not be a true reflection of modern surgical techniques. The meta-analysis included in this review may come under particular scrutiny due to the fact it encompasses all relevant data, regardless of quality. Throughout this review we have tried to minimize selection and reporting bias by presenting our work and findings in a transparent, reproducible and open manner. We have also allowed our readers to come to their own conclusions by presenting an objective analysis of our data.

Pooled proportion analysis of complications by country/continent of origin revealed the UK to a have statistically significant higher incidence of infection than continental Europe, Asia and the Americas and a statistically significant higher incidence of skin/wound healing problems than Asia and the Americas, but not continental Europe, ($p < 0.01$). This finding should be viewed with caution as the results from the Americas were hugely skewed by one study containing 25.7 percent of the entire patient population included in this review.[27] Secondly, as the studies had no standardised level of measuring outcomes, albeit with differing follow-up times or methods of recording a complication, it is difficult to assume that the UK has clinically significant problem with infection control or wound care. The difference may be attributable to the UK having a higher sensitivity in recording something as an ‘infection’ or a ‘wound problem’ compared with those studies conducted elsewhere which may not have recorded incidences which resolves spontaneously for instance. In many papers the definition of infection was either unreported or variably defined.

Likewise for our primary outcome, haematoma and/or bleeding, some articles reported only haematoma and some reported only bleeding. This may have meant that some articles potentially recorded serious haematomas, but not recorded minor bleeding as it might not have been viewed as a 'complication', hence underestimating the true level of haematoma and/or bleeding in the patient cohort. Upon comparison of surgical methodology, it seems that suture-based techniques have a higher incidence of revision surgeries/recurrence and lower incidence of skin/wound healing problems than cartilage manipulation. This is because the suture technique relies upon the suture to remain intact and the dissection required is also less than cartilage manipulation, and so wound healing problems (e.g. anterior skin necrosis) may be less. The data must be viewed with caution due to the small number of studies that were included to make this comparison.

The current findings are similar to historical studies: In 1994, Calder and Nasaan[48] reported a single centre cohort study of 562 consecutive cartilage manipulation otoplasties, with an incidence of bleeding of two percent, residual deformity in eight percent, infection in 5.2 percent, anterior skin necrosis in 1.4 percent, and pathological scarring in 2.1 percent. A study of 89 patients by Crikelair and Cosman[49] (1964) reported an incidence of haematoma of 1.1 percent, pathological scarring in 1.1 percent and wound healing complications in 3.4 percent. The majority of these historical results are within normal ranges established by the present review.

In conclusion, this review provides a contemporary summary of the incidence of common complications post-prominent ear correction. Thus this study can be used to provide a benchmark standard from which surgeons can audit current/novel otoplasty techniques and also to highlight the summative risks to patients and relatives pre-operatively – a fundamental aspect of delivering informed consent. Recommendations for future practice would include: prospective reporting of complications of otoplasty following a standardised checklist, with

length of follow-up recorded as both a range and mean. Further research in the format of multiple, multi-centred RCTs need to be undertaken to determine a statistically significant comprehensive profile of complication rates for each surgical method.

CONFLICT OF INTEREST

The authors state no conflict of interest.

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49. Crikelair GF, Cosman B. Another solution for the problem of the prominent ear. *Ann Surg.* 1964;160:314-24.

TABLE LEGEND

Table 1. Inclusion and exclusion criteria applied throughout the literature search, including the data extracted from the final articles. If an article included a sub-group of patients who met the criteria and could successfully be extracted from the final cohort, the article was included.

FIGURE LEGENDS

Figure 1. Flow diagram illustrating search methodology for inclusion of articles in the systematic review.

Figure 2. Forrest plot displaying the proportion of reported haematoma and/or bleeding post-prominent ear correction (3493 patients in 28 studies). Results of individual studies are provided in the body of the figure; the summary statistic of the random-effects model shows the incidence of haematoma and/or bleeding when all studies are combined in the meta-analysis model.

Figure 3. Continent/country of origin of included studies with data shown as total number of patients (n) and pooled proportion of haematoma and/or bleeding. CI = confidence interval.

APPENDIX ONE

Outcome measures and quality (MINORS and Detsky) scores for each study in the meta-analysis.

	Inclusion criteria	Exclusion criteria	Data extracted
Population	Human. Patients with prominent ears undergoing otoplasty. All ages. Any country of origin. Full-text article in an English language journal.	Non-human. Patients with other congenital ear deformities. Abstracts; review articles; conference articles in non-English language journals. Publications prior to 01/01/2000.	Patients (n). Age at operation. Country of origin. Author; journal; year of publication.
Intervention	Otoplasty (including revision surgeries). All surgical techniques. Study cohort ≥20 patients.	Combined procedures (when otoplasty is performed alongside other procedures simultaneously). Study cohort <20 patients.	Surgical technique; number of surgeons involved in the study.
Comparator	Different management protocols	None	Patients (n) per comparative study group
Outcome	Primary outcome: haematoma and/or bleeding. Secondary outcomes: infection; skin/wound healing problems; suture-related problems; scarring; pain and itching; revision/recurrence.	No haematoma and/or bleeding incidence recorded.	Haematoma and/or bleeding (n). Infection (n); skin/wound healing problems (n); suture-related problems (n); scarring (n); pain and itching (n); revision/recurrence (n).
Study design	Randomized or non-randomized studies; comparative or non-comparative studies.	Non-clinical studies; case reports; small case series.	Study design; length of follow-up.

Figure 1

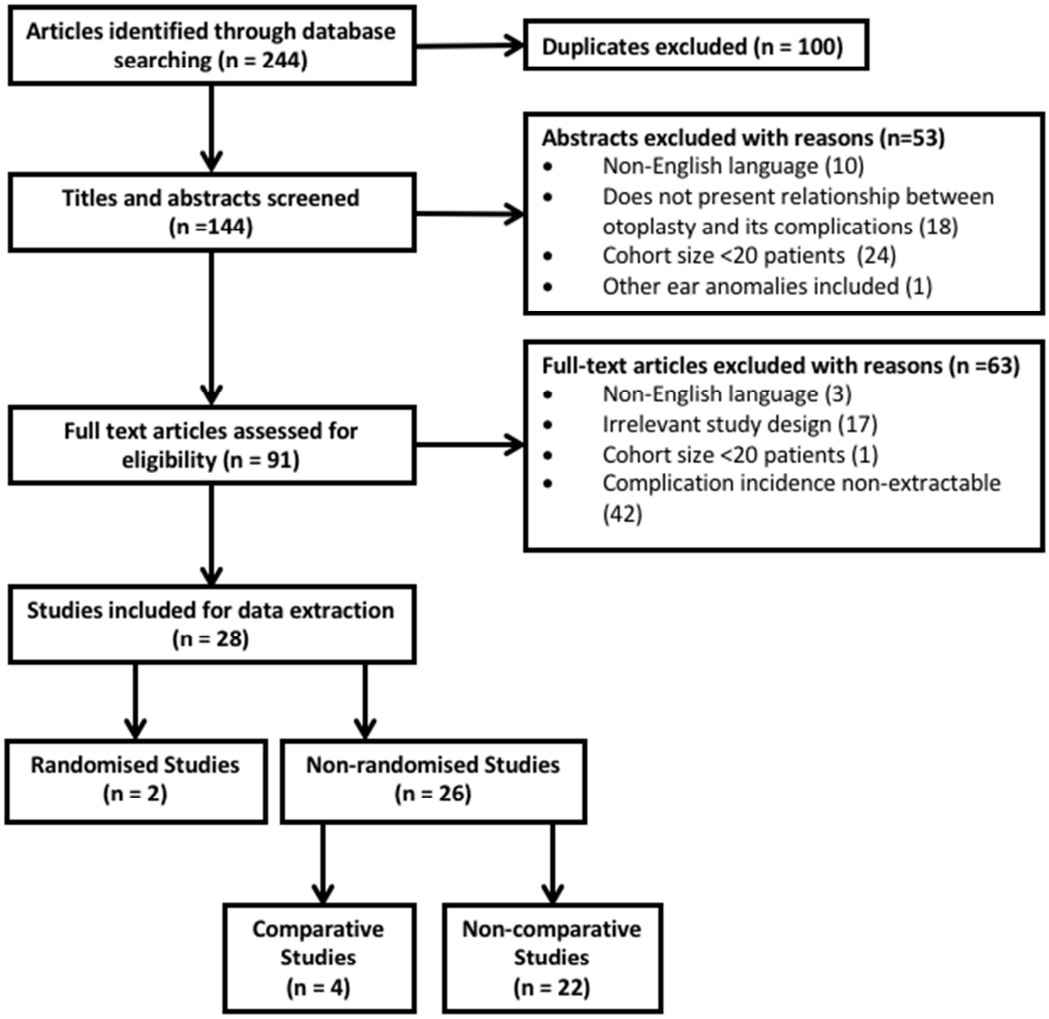

Articles identified through database searching (n = 244)
Duplicates excluded (n = 100)
Titles and abstracts screened (n =144)
Abstracts excluded with reasons (n=53)
Non-English language (10)
Does not present relationship between otoplasty and its complications (18)
Cohort size <20 patients (24)
Other ear anomalies included (1)
Full text articles assessed for eligibility (n = 91)
Full-text articles excluded with reasons (n =63)
Non-English language (3)
Irrelevant study design (17)
Cohort size <20 patients (1)
Complication incidence non-extractable (42)
Studies included for data extraction (n = 28)
Randomised Studies (n = 2)
Non-randomised Studies (n = 26)
Comparative Studies (n = 4)
Non-comparative Studies (n = 22)

Figure 2

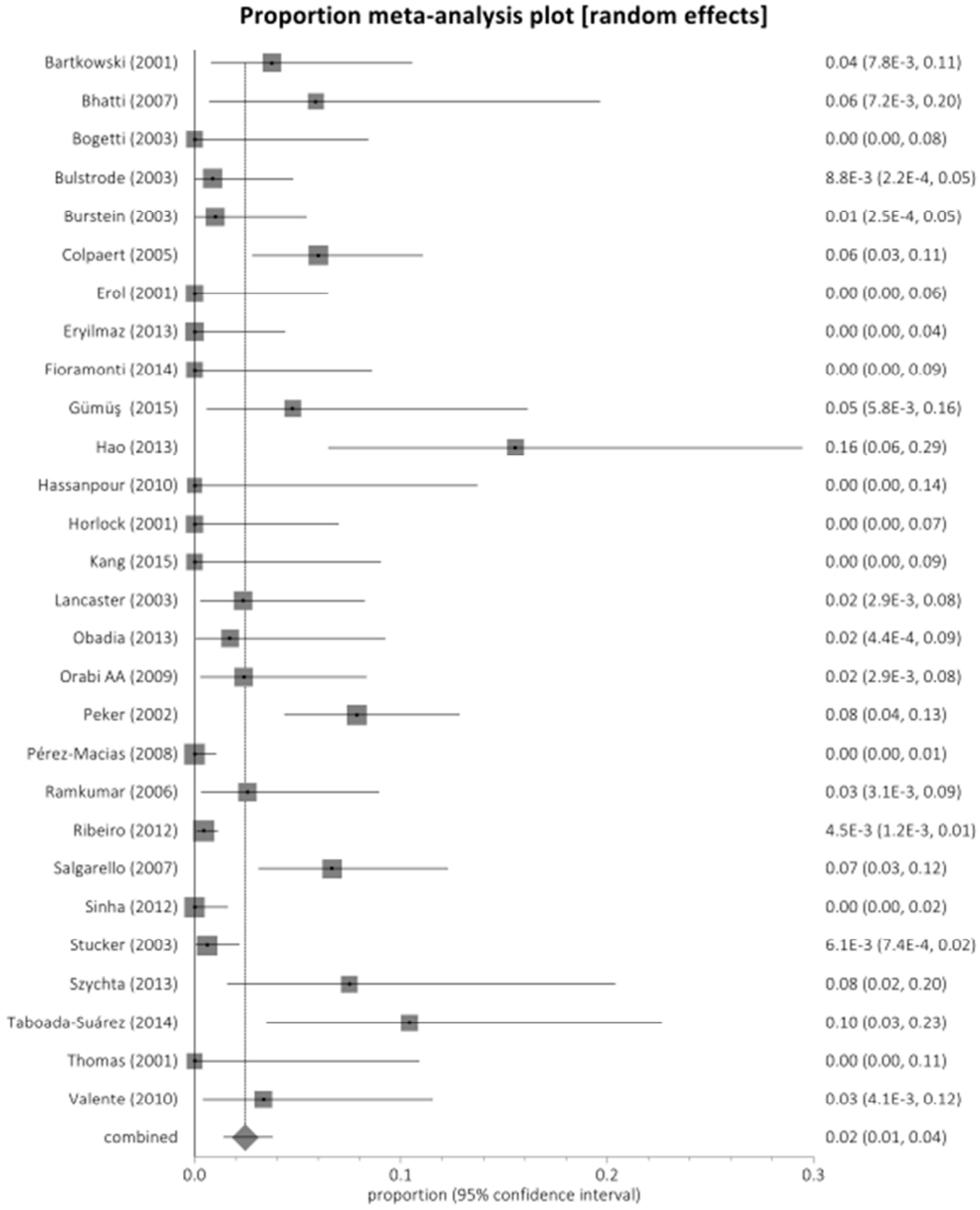
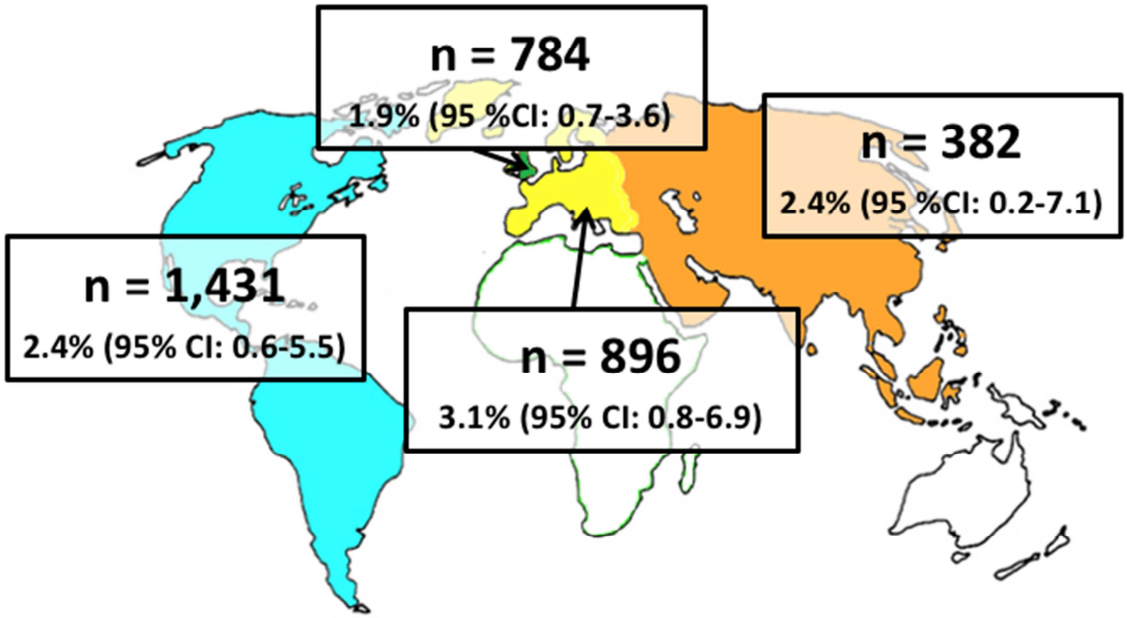

Proportion meta-analysis plot [random effects]
Bartkowski (2001) 0.04 (7.8E-3, 0.11)
Bhatti (2007) 0.06 (7.2E-3, 0.20)
Bogetti (2003) 0.00 (0.00, 0.08)
Bulstrode (2003) 8.8E-3 (2.2E-4, 0.05)
Burstein (2003) 0.01 (2.5E-4, 0.05)
Colpaert (2005) 0.06 (0.03, 0.11)
Erol (2001) 0.00 (0.00, 0.06)
Eryilmaz (2013) 0.00 (0.00, 0.04)
Fioramonti (2014) 0.00 (0.00, 0.09)
Gümüş (2015) 0.05 (5.8E-3, 0.16)
Hao (2013) 0.16 (0.06, 0.29)
Hassanpour (2010) 0.00 (0.00, 0.14)
Horlock (2001) 0.00 (0.00, 0.07)
Kang (2015) 0.00 (0.00, 0.09)
Lancaster (2003) 0.02 (2.9E-3, 0.08)
Obadia (2013) 0.02 (4.4E-4, 0.09)
Orabi AA (2009) 0.02 (2.9E-3, 0.08)
Peker (2002) 0.08 (0.04, 0.13)
Pérez-Macias (2008) 0.00 (0.00, 0.01)
Ramkumar (2006) 0.03 (3.1E-3, 0.09)
Ribeiro (2012) 4.5E-3 (1.2E-3, 0.01)
Salgarello (2007) 0.07 (0.03, 0.12)
Sinha (2012) 0.00 (0.00, 0.02)
Stucker (2003) 6.1E-3 (7.4E-4, 0.02)
Szychta (2013) 0.08 (0.02, 0.20)
Taboada-Suárez (2014) 0.10 (0.03, 0.23)
Thomas (2001) 0.00 (0.00, 0.11)
Valente (2010) 0.03 (4.1E-3, 0.12)
combined 0.02 (0.01, 0.04)
0.0
0.1
0.2
0.3
proportion (95% confidence interval)

Figure 3


n = 784
1.9% (95 %CI: 0.7-3.6)
n = 382
2.4% (95 %CI: 0.2-7.1)
n = 1,431
2.4% (95% CI: 0.6-5.5)
n = 896
3.1% (95% CI: 0.8-6.9)