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BALLOON EUSTACHIAN TUBOPLASTY FOR TREATMENT OF EUSTACHIAN TUBE DYSFUNCTION

HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS)
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DISCLOSURE

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EXECUTIVE SUMMARY

Background

Eustachian Tube Dysfunction (ETD) is a frequent middle ear problem causes by either structural, functional or both such as patency of tube, inflammation, chronic sinusitis, allergic rhinitis, adenoid hypertrophy, tobacco smoke, cleft palate and others. It can lead to chronic condition like otitis media with effusion, atelectasis of middle ear, adhesive otitis, and perforation of ear drum and may eventually lead to development of cholesteatoma.

The incidence of ETD is very common in young children with a rate of 30-80% during childhood and it's substantially reduced to about 1 % in adulthood based on the study done among British population. Symptoms that are associated with ETD are muffled hearing, otalgia, tinnitus, vertigo and fullness of ear.

There are many approaches to diagnose and assess the severity of ETD such as using otoscopy, audiometry, tubomanometry, and also using scoring method such as Eustachian tube score (ETS), and others. Eustachian tube dysfunction symptoms can be treated by medical treatment, surgical procedure or both. Medical treatment included oral and nasal steroid, decongestant and antihistamine and if ETD persists, surgical procedure like ventilation tube, laser tuboplasty and others can be offered. However, the recurrent tube insertion in certain cases will subject the patient to crusting, infection, obstruction, permanent tympanic membrane perforation and tympanic membrane scarring.

Balloon Eustachian Tuboplasty (BET) is a new technology which was introduce to treat the symptom of ETD that involve the insertion of balloon catheter via the nose under transnasal endoscopic vision. The aim of the procedure is to widen the Eustachian tube and improve its function.

This technology review was requested by a Consultant of Otorhinolaryngology Department, Head and Neck Surgery, Hospital Taiping to review the evidence on BET for treatment of ETD.

Objective/aim

To assess the safety, effectiveness, cost-effectiveness and organisational aspect of BET for treatment of ETD.

Results and conclusions

A total of 18 titles were identified through the Ovid interface and PubMed. There were five articles included in this review; a systematic review, a randomised control trial (RCT), and three pre-and post-intervention studies. However, there

was no retrievable evidence from the scientific databases on cost-effectiveness and organisational aspect of this technology.

1) Efficacy/Effectiveness
   - There were limited fair level of retrievable evidence on BET in the treatment of ETD.
   - Evidence suggests that BET was effective in reducing ETD symptoms and improving hearing function in mild and chronic ETD patients.
2) Safety
   - There were no major complications (mortality and morbidity) reported with the use of BET for treatment of ETD.
   - However, there were minor complications such as epistaxis, emphysema, acute otitis media, retraction of tympanic membrane and mild rhinitis symptoms post operatively.
   - This technology has been certified by DQS Medizinprodukte GmbH under Annex V of Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.
3) Cost and Cost-effectiveness
   - There was no evidence retrieved on cost and cost-effectiveness of this technology.
   - The price for BET catheter set is RM 2862.00.
4) Organisational
   - There was no retrievable evidence on organisational aspect of BET for treatment of ETD.

Methods

Literature search was done to search for published articles to assess the safety, efficacy or effectiveness and cost-effectiveness of BET for treatment of ETD. The following electronic databases were searched via OVID Interface: MEDLINE (1946 to 7 September 2015), EBM Reviews-Cochrane Database of Systematic Reviews (2005 to August 2015), EBM Reviews-Cochrane Central Register of Controlled Trials (August 2015), EBM Reviews–Database of Abstracts of Review of Effects (3rd Quarter 2015), EBM Reviews-Health Technology Assessment (3rd Quarter 2015) NHS economic evaluation database (3rd Quarter 2015), Pubmed and USFDA database. The last search was run on 7 September 2015.

Balloon Eustachian Tuboplasty for Treatment of Eustachian Tube Dysfunction

1. INTRODUCTION

Eustachian Tube Dysfunction (ETD) is a frequent middle ear problem causes by either structural, functional or both such as patency of tube, inflammation, chronic sinusitis, allergic rhinitis, adenoid hypertrophy, tobacco smoke, cleft palate and others. It can lead to chronic condition like otitis media with effusion, atelectasis of middle ear, adhesive otitis, and perforation of ear drum and may eventually lead to development of choleasteatoma.[1]

The incidence of ETD is very common in young children with a rate of 30-80% during childhood and it's substantially reduced to about 1 % in adulthood based on the study done among British population.[2] Symptoms that are associated with ETD are muffled hearing, otalgia, fullness of ear, tinnitus and vertigo.[3]

There are many approaches to diagnose and assess the severity of ETD such as using otoscopy, audiometry, tubomanometry, and also using scoring method such as Eustachian tube Score (ETS), and others. ETD symptoms can be treated by medical treatment, surgical procedure or both. Medical treatment included oral and nasal steroid, decongestant and antihistamine and if ETD persists, surgical procedure like ventilation tube, laser tuboplasty and others can be offered. However, the recurrent tube insertion in certain cases will subject the patient to crusting, infection, obstruction, permanent tympanic membrane perforation and tympanic membrane scarring.[3]

Balloon Eustachian Tuboplasty (BET) is a new technology which was introduce to treat the symptoms of ETD that involve the insertion of balloon catheter via the nose under transnasal endoscopic vision. The aim of the procedure is to widen the Eustachian tube and improve its function.[3]

This technology review was requested by a Consultant of Otorhinolaryngology Department, Head and Neck Surgery, Hospital Taiping to review the evidence on BET for treatment of ETD.

2. OBJECTIVE / AIM

To assess the safety, effectiveness, cost-effectiveness and organisational aspect of BET for treatment of ETD.

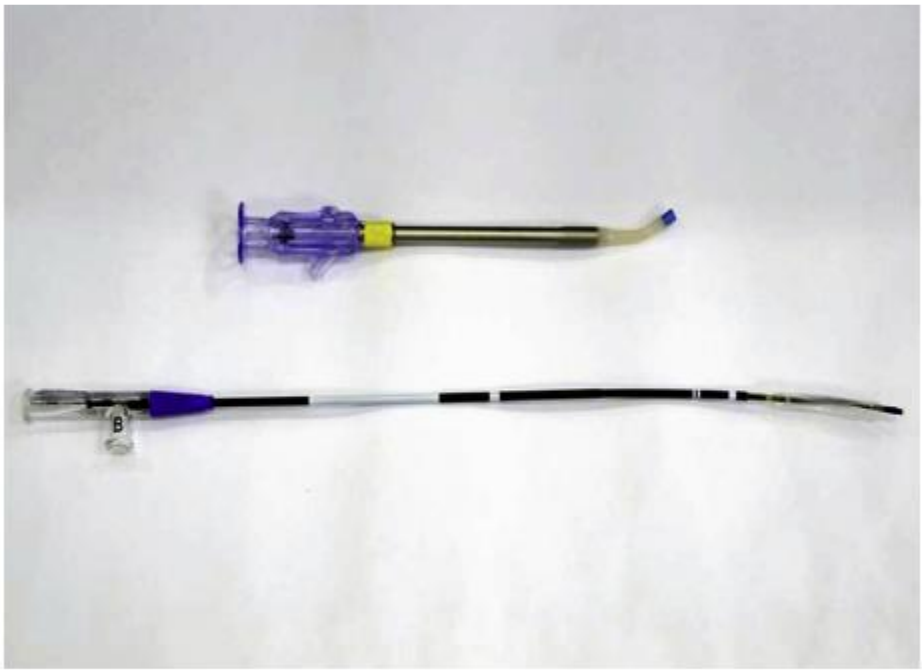
3. TECHNICAL FEATURES

3.1 What is Balloon Eustachian Tuboplasty?

Balloon Eustachian Tuboplasty (BET) is an instrument that introduces the balloon catheter into the Eustachian tube via the nose under transnasal endoscopic vision mainly to widen the Eustachian tube and improve its function. It is usually perform with the patient under general anaesthesia.[4]

The main instrument is the balloon catheter with an inflatable balloon near the distal tip. It has Luer-lock for inflation and deflation with two x-ray contrast marker to show the cylindrical part of the balloon on the x-ray. The balloon catheter needs to be attached to an inflation pump to inflate the balloon during the procedure (Figure 1).[4]

Figure 1: The balloon and the catheter

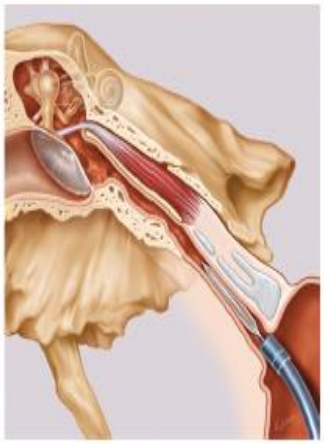


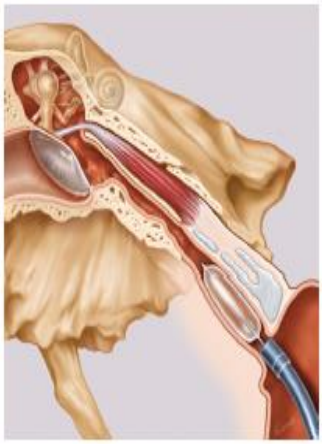
3.2 Mechanism of action

The endoscopic camera will be inserted through the nose either by contralateral access (opposite nostril with balloon catheter), ipsilateral access (same nostril with balloon catheter) or phyrygeal access (via oral cavity).Then, the balloon catheter will be introduced endonasally on the side to be treated using the insertion instrument and placing it within the ostium of Eustachian tube. The

catheter will be connected to an inflation pump and it is fill with saline up to a pressure of about 10 bars. The pressure will maintain for two minutes while the balloon catheter dilates the compromise area of the Eustachian tube. The balloon is then empty and removes (Figure 2).[4]

Figure 2: The insertion of balloon catheter and dilatation of Eustachian tube


Inserting the catheter


Dilating the auditory tube

4. METHODS

4.1 Searching

Electronic databases searched through the Ovid interface:

- MEDLINE (R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present
- EMBASE – 1996 to 2015 September 6
- EBM Reviews- Cochrane Central Registered of Controlled Trials- August 2015
- EBM Reviews- Database of Abstracts of Review of Effects- 2nd Quarter 2015
- EBM Reviews- Cochrane Database of Systematic Reviews- 2005 to August 2015
- EBM Reviews- Health Technology Assessment- 3rd Quarter 2015
- EBM Reviews- NHS Economic Evaluation Database- 3rd Quarter 2015

Other databases:

- Pubmed
- US FDA
- Other websites: INAHTA

Additional articles were identified from reviewing the references of retrieved articles. General search engine was used to get additional web based

information. The search was limited to articles on human. There was no language limitation in the search. Appendix 1 showed the detailed search strategies. The last search was conducted on 7 September 2015.

4.2 Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patients with Eustachian Tube Dysfunction (ETD)
Interventions	Balloon Eustachian Tuboplasty (BET)
Comparators	Myringoplasty/ventilation tube/any comparator or no comparator
Outcomes	1) Efficacy/effectiveness - Improvement in ETD symptom(severity or frequency) - Improvement in hearing function - Quality of life (QoL) 2) Safety -Adverse event (e.g. bleeding, emphysema) -Discomfort during procedure 3) Cost and cost-effectiveness 4) Organisational - Training of staff - Reduce length of stay
Study design	Systematic review (SR),Health Technology Assessment (HTA), Randomised controlled Trial (RCT),Cohort Study, Case Series and Case Report
	English full text articles

Exclusion criteria

i) Animal study / laboratory study
ii) Narrative review
iii) Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5. RESULTS AND DISCUSSION

A total of 18 titles were identified through the Ovid interface and PubMed. There were five articles included in this review; a systematic review, a RCT and three pre-and post-intervention studies. However, there was no retrievable evidence from the scientific databases on cost-effectiveness and organisational issue of this technology. The studies retrieved and included in this review were conducted using either Biefield Balloon System (length 20, diameter 3.28m), Reliva Solo Sinus Balloon System (length 16m, diameter 7 mm) or Reliva Vortex Sinus Irrigation Catheter (length 16, diameter 5 mm).

5.1 EFFICACY / EFFECTIVENESS

5.1.1 Hearing Function

Randrup TS and Oversen T (2015) conducted a systematic review for studies published from January 1, 2010 to April 7, 2014 to evaluate the effectiveness of BET for treatment of ETD. Nine case series were included with a total of 443 patients. Studies included were; Ockermann 2010, Poe 2011, McCoul 2012, Schroder 2012, Catalano 2012, Jurkiewicz 2012, Tiscth 2013, Bast 2014 and Silvova 2014. The criteria of patients differ widely across the studies and in most studies there were limited information on preoperative medication or continuation of decongestant or nasal steroid after the surgery.[1,Level II-I]

In the study, the outcome for hearing function were measured by tympanometry, Vasalva test, Swallowing test and Eustachian tube score (ETS).The tympanometry measures the acoustic admittance of the middle ear as a function of air pressure change in the external ear canal. Five studies showed a high rate of conversion of type B or type C into type A(normal) tympanometry at follow up (range, six weeks to 1.5 years). The Vasalva and Swallowing test measures the middle ear function by inspecting the tympanic membrane. Both tests showed positive effect at all available endpoints (range six weeks to 1.5 years).The ETS is a scoring method which combined the results of tubomanometry, Vasalva test and Swallowing test with a score range: 0 (poor Eustachian tube function) to 10(normal Eustachian tube function); score above five indicating functional Eustachian tube. It showed significant improvement at all follow up (range eight weeks to 12 months).[1, level II-1]

Ahmad MA (2013) conducted a RCT at Benha University Hospital, Egypt mainly to evaluate the effect of BET on the results of surgical reconstruction of subtotal tympanic membrane perforation in cases of resistant ETD. The study included 76 patients with dry subtotal perforations (perforations > 75% of tympanic membrane size and not reaching the annular ligament) with resistant ETD (resistant of full course of medical treatment such as nasal decongestant, anti-histamine and corticosteroids). Patients were randomly divided into two groups: A and B with 38 patients in each groups using sealed envelopes. Group A patient undergo myringoplasty with BET while Group B only received myringoplasty without any other procedure and both groups were follow up after 1^{st},2^{nd},4^{th} weeks then after six and 12 months.[5,Level II-1]

The outcome measures in this study were pure tone audiometry frequency (250-8000 Hz), air-bone gap and middle ear pressure. Pure tone audiometry results at 12 months postoperatively showed a significant improvement of air conduction curves at all frequencies in both groups with slight better results in group A ($P<0.05$). There were no significant changes in the bone conduction curves. The mean air-bone gap in groups A and B showed significant improvement from 30.08 to 9.25 dB in group A and from 29.65 to 9.85 dB in group B. The middle ear pressure was significantly better in group A at six months (mean pressure:-29 daPa in group A,-60 daPa in group B) and at 12 months (mean pressure:-55daPa in group A,-79 daPa in group B).[5, Level II-1]

Gurtler N et al. (2014) conducted a pre-and post-intervention study at University Hospital Basel, Switzerland to assess BET for treatment of ETD. The study included 21 patients who were retrospectively analysed in the study. The outcome were measured pre-operative, one week and three months after the operative by ETS, R-value in tubomanometry, tympanograms, air bone gap and otomicroscopic findings.[2, Level II-3]

The results of ETS showed improvement of hearing in 67% of patients (reached score more than five points) after the procedure ($p\leq0.005$). Three R value by tubomanometry at 30,40 and 50 mbar noted to shift towards smaller value that was highly significant ($p<0.001$).The tympanogram showed conversion from type B and C to type A(normal) in 66.7% with a median score shift from two points preoperatively to four points post operatively ($p=0.0020$). The air bone gap measured in 19 patients showed significant improvement of 15 dB preoperatively to 10 dB postoperatively ($p=0.0078$).The otomicroscopic findings of 17 patients with retracted tympanic membranes grade I to II showed improvement of 18% while the rest remain unchanged.[2,Level II-3]

Wanscher JH and Svane-Knudsen V (2014) in their pre-and post-intervention study reported the effectiveness of BET in treatment of ETD. The study included 34 patients with 16 patients with bilateral problems (50 procedures) and they were having at least six months of ETD symptoms. The patients were classified

either having intermittent or chronic ETD. Four patients (bilateral ETD) were identified as intermittent ETD (mild ETD symptoms) and 30 patients were chronic ETD (chronic symptom, recurrent ear drum tube insertion, retraction of tympanic membrane, atelectasis). The effects were measured by otomicroscopy, tympanometry Toynbee test and ETD classification.[6, Level II-3]

The study found that in intermittent ETD patients, no hearing losses before and after the treatment by all hearing test. In patients with chronic ETD, post-operative otomicroscopy showed conversion to normal tympanic membrane in 42.1% patients with retracted tympanic membrane. However, no atelactasis cases were resolved. The air bone gap (conductive hearing loss) was seen in 82% of patients and post operatively changed from average of 28 dB to 18 dB ($p<0.05$) with no change in bone conduction. The tympanometry results of chronic ETD patients showed significant conversion to type A curve in 28% of patients post operatively. The Toynbee test which measured the change in pressure in the middle ear showed significant improvement of 77% in chronic ETD patients post operatively. The ETD classification measured the middle ear pressure equalisation ability of patients by subjectively and objectively (otomicroscopy). In chronic ETD patients, a significant improvement whereby 75% of patients moved to lower class (positive effect) post operatively.[6, Level II-3]

Jurkiewicz D et al. (2012) in their pre-and post-intervention study included four patients with the aim to assess the therapeutic effect of BET in the treatment of ETD. The outcome was measured by tympanometry, air-bone gap, Vasalva test and pressure swallow test six weeks post operatively. All patients reported an improvement of tympanometry result (conversion to type A) at six months post operatively. Three patients (75%) reported reducing in air-bone gap, however, there was one patient that only improved his right ear but the left ear has no changes. By Vasalva and swallowing test, three patients (75%) showed positive test .The authors concluded that even the study reported significant improvement in all parameters, there is a need for longer follow up study to determine the feasibility of BET in treatment of ETD.[7, Level II-3]

5.1.2 Eustachian Tube Dysfunction Symptoms

Systematic review by Randrup TS and Oversen T (2015) reported outcome of ETD symptoms by Eustachian Tube Dysfunction Questionnaire (ETDQ-7) in two studies. Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is a disease-specific symptoms score of ETD with score of one to seven (one indicated no problem and seven indicated severe problem) for each item related to ETD. The studies found a significant positive change in mean score of ETDQ-7 from 4.5 (SD, 1.2) to 2.8 (SD, 1.3) at six months follow up ($P<0.001$*).* However, a large proportion of the included patients had adjunctive surgery but there were no significant difference in ETDQ-7 scores could be found between this group and the group who had only BET ($P=0.34$).[1, Level II-1]

Gurtler N et al. (2014) in pre-and post-intervention study measured the subjective improvement in ETD symptoms by four elements; pressure symptom, hearing impairment, vertigo and tinnitus. The study found that there was a significant improvement of all symptoms perceived by 71% of patients after one week and by 76% after three months post operatively.[2, Level II-3]

The pre-and post-intervention study by Wanscher JH and Svane-Knudsen V (2014) measured ETD symptoms by visual analogue scale (VAS) questionnaire which included the patient's ability to do Vasalva test and their experienced of having aural fullness or earache. The VAS questionnaire showed significant improvement ($p<0.05$) in all element where 66% patients indicates positives effect on doing Vasalva test, 55% indicates positive effect on earache and 48% indicates positive effect of aural fullness.[6,Level II-3]

5.1.3 Quality of Life (QoL)

Randrup TS and Oversen T reported the effect in quality of life (QoL) by 22-item sino-nasal outcome test (SNOT-22) and Glascow benefit inventory (GBI) questionnaire. The SNOT-22 is a disease specific QoL measurement tools for patients with rhinosinusitis since there were overlapped symptoms between rhinosinusitis and ETD. The results showed significant reduction in SNOT-22 from a mean of 51.4 (SD, 21.1) to 30.0 (SD, 23.9) at six months *(*P=0.001).The GBI in the other hand, measured the change in health status produced by surgical interventions. There was an increased in the median value of the total GBI score (P=0.001) and in subgroup general health (P=0.001) and physical health (P=0.039).[1, Level II-1]

5.2 SAFETY

Systematic review by Randrup TS and Oversen T reported no severe morbidity or mortality due to adverse event directly attributed to BET in all nine studies. Two cases of emphysema were reported. There were reports of minor epistaxis in two studies and temporarily increased tinnitus was noted in one study.[1, Level II-I]

Ahmed MA in the RCT reported no sensorineural hearing loss, facial palsy, blunting and lateralization in both groups. No occurrence of patulous tube in any cases. However, there was tympanic membrane retraction of grade II occurred in two cases of Group A (5.4%) and in nine cases in group B (25.7%) post operatively.[5,Level II-I]

Gurtler N et al. reported one minor bleeding complication which controlled by nasal tamponade for 12 hours and about half of subjects reported rhinitis-like symptom (such as congested nose - rhinorrhoea) for one to five days post operatively.[2, Level II-3]

Wanscher JH and Svane-Knudsen reported acute otitis media cases in 10 % of patients post operatively. No other complication such as bleeding or emphysema were noted in all patients.[6, Level II-3]

Jurkiewicz et al. also reported no adverse event (such as bleeding or damage to the regional mucosa) seen in all four patients who were treated with BET six weeks post operatively.[7, Level II-3]

This technology has been certified by DQS Medizinprodukte GmbH under Annex V of Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.However, there was no retrieval evidence from the United States Food and Drug Administration (USFDA) for this technology.

5.3 COST-EFFECTIVENESS

There was no retrievable evidence from the scientific databases on the cost-effectiveness of using Balloon Eustachian Tuboplasty for treatment of Eustachian tube dysfunction. However, the price of BET Catheter set is RM 2862.00.

5.4 ORGANISATIONAL

There was no retrievable evidence from the scientific databases on organizational aspect of this technology.

5.5 LIMITATIONS

This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English full text articles were included in this report. However, there was no study to compare BET with the usage of short term and long term ventilation tube (current technology).

6. CONCLUSION

There was limited fair level of retrievable evidence to suggest the effectiveness and safety of BET for treatment of ETD. The evidence suggests that BET was effective in reducing ETD symptoms and improving hearing function in mild and chronic ETD patients. There were no mortality or severe morbidity reported with the use of BET for treatment of ETD. However, there were minor complications such as epistaxis, emphysema, acute otitis media, retraction of tympanic membrane and mild rhinitis symptoms reported post operatively. No retrievable evidence on cost-effectiveness and organisational aspect of this technology. However, the price of BET Catheter set is RM 2862.00.

7. REFERENCES

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6. Wanscher JH, Svane-Knudsen V. Promising results after balloon dilatation of the Eustachian tube for obstructive dysfunction. Danish Med J. 2014; 61(4):A4818.

7. Jurkiewicz D, Bień D, Szczygielski K, Kantor I. Clinical evaluation of balloon dilation Eustachian tuboplasty in the Eustachian tube dysfunction. Eur Arch Otorhinolaryngol. 2013; 270(3):1157-60.

8. APPENDIX

8.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1946 to present

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 EUSTACHIAN TUBE/ (2955)
2 (tube* adj1 (auditory or Eustachian or pharyngotympanic)).tw. (3281)
3 Eustachian tube dysfunction/ (0)
4 eustachian tube dysfuction.tw. (0)
5 OTITIS MEDIA/ (15748)
6 (middle ear adj1 inflammation).tw. (190)
7 otitis media.tw. (17466)
8 OTITIS MEDIA WITH EFFUSION/ (5034)
9 ear effusion* middle.tw. (4)
10 (middle ear adj1 effusion*).tw. (1756)
11 (otitis media adj1 (secretory or serous)).tw. (1415)
12 otitis media with effusion.tw. (2638)
13 1 or 2 or 3 or 4 or 5 or 7 or 8 or 9 or 10 or 11 or 12 (28041)
14 Balloon eustachian tuboplasty/ (0)
15 Balloon eustachian tuboplasty.tw. (5)
16 balloon dilatation/ (0)
17 balloon dilatation.tw. (3234)
18 14 or 15 or 16 or 17 (3237)
19 13 and 18 (17)

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Database of Abstracts of Review of Effects	
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
EBM Reviews- NHS economic evaluation database	
INAHTA	Balloon Eustachian Tuboplasty

PubMeD

Search ((((((((((((((((((((((((((((EUSTACHIAN TUBE[MeSH Terms]) OR auditory tube[Title/Abstract]) OR tubes auditory[Title/Abstract]) OR auditory tubes[Title/Abstract]) OR tube auditory[Title/Abstract]) OR eustachian tubes[Title/Abstract]) OR tubes eustachian[Title/Abstract]) OR tube eustachian[Title/Abstract]) OR eustachian tube[Title/Abstract]) OR pharyngotympanic tubes[Title/Abstract]) OR pharyngotympanic tube[Title/Abstract]) OR tube pharyngotympanic[Title/Abstract]) OR tubes pharyngotympanic[Title/Abstract]) OR Eustachian tube dysfunction[Title/Abstract]) OR OTITIS MEDIA[MeSH Terms]) OR middle ear inflammation[Title/Abstract]) OR inflammation middle ear[Title/Abstract]) OR otitis media[Title/Abstract]) OR OTITIS MEDIA WITH EFFUSION[Title/Abstract]) OR ear effusions middle[Title/Abstract]) OR ear effusion middle[Title/Abstract]) OR middle ear effusions[Title/Abstract]) OR effusion middle ear[Title/Abstract]) OR middle ear effusion[Title/Abstract]) OR effusions middle ear[Title/Abstract]) OR secretory otitis media[Title/Abstract]) OR otitis media serous[Title/Abstract]) OR otitis media secretory[Title/Abstract]) OR serous otitis media[Title/Abstract]) OR otitis media with effusion[Title/Abstract])) AND Balloon eustachian tuboplasty[Title/Abstract]

8.2. Appendix 2

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomize controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

8.3. Appendix 3

Evidence Table : Efficacy/ Effectiveness
Question : Is Balloon Eustachian Tuboplasty (BET) effective in treatment of Eustachian Tube Dysfunction?

Bibliographic Citation	Study Type / Methods	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Randrup TS, Ovesen T. Balloon eustachian tuboplasty: a systematic review. Otolaryngol Head Neck Surg. 2015; 152(3):383-92.	Systematic review <u>Aim</u> -To evaluate the effectiveness and safety of BET in treatment and improving of ETD symptoms. <u>Review method</u> Database was searched using search term: EMBASE, PubMed, Web of Science, Cochrane Library, HTA Database, NHS Economic Evaluation Database and others related databases from January 2010 to current with no restriction on study design or sample size. All procedure were performed under general anaesthesia except one study was done under local anaesthesia	II-1	Nine case series : - Ockermann(2010) -Poe (2011) -Mc Coul (2012) -Schroder (2012) -Catalano (2012) -Jurkiewicz (2012) -Tisch (2013) -Bast (2014) -Silvova (2014) 443 patients (642 Eustachian tube) were included. The population size range from n=4 (7 Eustachian tube) to n=210 (320 Eustachian tube). All patients are adults. .	Balloon Eustachian Tuboplasty (BET)	-	Average length of follow up : one week to 1.5 years	**Patients' symptom using ETD Questionnaire (ETDQ-7) in Mc Coul (2012).** -results found a significant, positive change in the mean score of ETDQ-7 from 4.5 (SD, 1.2) to 2.8 (SD, 1.3) at 6 month ($p<0.01$). **Tympanometry in Catalano, Jurkiewicz, McCoul, Poe and Silvova** -the results of tympanometry shows a high rate of conversion of Type B or C into Type A at follow up (range,6 weeks-1.5 years). **Mucosal inflammation at tubal orifice in Poe and Silvova** **-**shows a significant reduction in in inflammation at 6 month and 1.5 years. **Vasalva test in Ockermann, Jurkiewicz, Poe, Silvova and Tisch. The swallowing test in Ockermann**, -Vasalva 's test shows a positive effect in all available endpoint range (6 weeks to 1.5 years) and the swallowing test results correlate with those of Vasalva Test.	Positive outcome in majority of the study.

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	-Nine case series were included with 443 patients. -Study quality was assesses using modified Delphi technique quality appraisal tool for Case Series. Risk of Bias was assessed using Cochrane Collaboration's Tool						**Eustachian Tube Score (ETS) in Ockermann and Schroder** -The studies showed significant improvement at all follow up (range, 8 weeks to 12 month). **Sino Nasal Outcome Test (SNOT-22) in Mc Coul** -The study found the significant reduction in 22 item of the score from a mean of 51.4 (SD, 21.1) to 30.0 (SD, 23.9) at 6 month (p=0.001). **Glasgow benefit Inventory (GBI Score) for Quality of Life (QoL) in Bast** -The study found that increase QoL in 30 patients (88% response) at range of 6 to 18 month. -There was also increase in the median value of the total GBI score (P=0.001) and in sub general health (p=0.001) and physical health (p=0.039). **Conclusion by authors** All studies included were case series that has high risk of bias and poor study design.The evidence suggest some benefit of BET and some measures support the feasibility and safety of BET .However, no absolute indication for procedure can be identified.	

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2. Ahmad MA. Does balloon Eustachian tuboplasty increase the success rate in repair of subtotal tympanic membrane perforations with resistant tubal dysfunction? Egyption Journal of ear, Nose, Throat and Allied Science.2013; 14:97-101.	Randomised Controlled Trial Aim To evaluate the effect of BET on the results of surgical reconstruction of subtotal tympanic membrane perforation in cases of Eustachian tube Dysfunction. Method Seventy two patients with dry subtotal tympanic membrane perforation and resistant Eustachian tube dysfunction, aging 19 to 51 years were distributed randomly into two groups A and B (using sealed enveloped) Both groups underwent myringoplasty using temporalis fascia graft. In group A, myringoplasty was proceed by BET. All procedure was done under general anaesthesia	II-1	Seventy- two patients were enrolled. Patients' age: 19-51 years. Patients with subtotal perforation (perforation >75% of tympanic membrane and not reach the annular ligament), dry for at least 3 month, bad Eustachian tube function resistant to full course of medical treatment, conductive hearing loss correlating with the perforation.	Myringoplasy + BET	Myringoplasty	12 months	**Pure Tone Audiometry** Showed a significant improvement of air conduction curve at all frequencies in both groups with slight better results in group A. No significant changes in the bone conduction curve. **Air-Bone Gap (ABG)** The mean of ABG in groups A and B showed a significant improvement from 30.08 to 9.25 dB in group A and from 29.65 to 9.85 dB in Group B. **The middle-ear pressure** The middle ear pressure was better in Group A at 6 month (mean pressure:-29daPa in group A,-60 da Pa in Group B) and at 12 months postoperative (mean pressure:-55 daPa in group A -79 daPa in group B) **Conclusion by author** BET is safe, easy and effective procedure that yields better results in reconstruction of subtotal tympanic membrane perforations in ETD without complication.	

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3. Gürtler N, Husner A, Flurin H. Balloon dilation of the Eustachian tube: early outcome analysis. Otology Neurotology. 2015;36(3):437-43	Pre-and post-intervention study <u>Aim</u> To assess BET in treatment of ETD <u>Method</u> A total of 21 patients with ETD who was treated with Eustachian Tube Balloon Dilatation were retrospectively analysed. The data was collected pre-operatively and 1 week and 3 month post-operative and the outcome were measured. All procedure was done under general anaesthesia.	II-3	21 patients were enrolled. Mean age of 37.5,range 19-67 14 males and 7 females. All patients was diagnosed with ETD by history, otoscopy, pure tone audiometry, impedance audiometry and tubomanomatry. A CT scan was obtained preoperatively to rule out bony dehiscence of the carotid artery and anomalies of Eustachian Tube	Balloon Eustachian Tuboplasty	-	Three months	**Eustachian Tube Score (R-value/ tympanogram/ air-bone gap)** Eustachian tube Score showed a statistically significant positive outcome ($p<0.005$) after BET treatment. Subjective improvement was seen in 76%. Normal R-values were achieved in 57%. Retraction process of the tympanic membrane improves in 18%.	

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4. Wanscher JH, Svane-Knudsen V. Promising results after balloon dilatation of the Eustachian tube for obstructive dysfunction. Dan Med J. 2014;61(4):A4818.	Pre-and post-intervention study <u>Aim</u> To evaluate effectiveness and safety of Balloon Eustachian Tuboplasty in Eustachian Tube Dysfunction <u>Method</u> Patients with Eustachian Tube Dysfunction for at least 6 month were included (34 patients;16 patients had bilateral problem) Patients were assessed using audiometry, tympanometry and Tonybee's test pre operatively and after 2 months of BET procedure. In most cases, the procedure was done under general anaesthesia combined with extensive application of local anaesthesia and vasoconstriction in nasal cavity. The procedure in local anaesthesia alone only in three cases.	II-3	34 patients were enrolled from June 2012 to May 2013. Patients' age: 20 – 74 years. Patients were at least six month of Eustachian Tube Dysfunction symptom or had ETD symptom during flying, diving and/or secretary otitis media several times per year during even a mild upper respiratory infection as seen by an ENT doctor.	Balloon Eustachian Tuboplasty	-	Two months	**Audiometry/Tympanometry/ Toynbee test** A significant positive results in all test after BET treatment **Audiometry** In intermittent ETD: no hearing losses before and after treatment. In Chronic ETD: an air-bone gap in 82% of the ears.42% of those had either no air-bone gap or a smaller air bone gap post operatively. In atelectasis patient: no hearing improvement post-operatively. **Tympanometry** In intermittent ETD: Normal tympanometry in pre-operative and post operatively. In chronic ETD: 58% of the patients showed positive change post operatively **Toynbee Test** In intermittent ETD: Normal test in preoperative and post operative. In chronic ETD: Positive test was seen in 70 % post operatively. **Visual Analogue Score (VAS)** A significant improvement ($p<0.05$) seen post operatively. Positive Vasalva Test: 66% Positive effect on ear ache:55% Positive effect in aural fullness:48%	

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5. Jurkiewicz D, Bień D, Szczygielski K, Kantor I. Clinical evaluation of balloon dilation Eustachian tuboplasty in the Eustachian tube dysfunction. Eur Arch Otorhinolaryngol. 2013 Mar;270(3):1157-60	Pre-and post-intervention study <u>Aim</u> To assess the benefit of BET in the treatment of ETD that caused by disorder in the middle ear ventilation <u>Method</u> Four patients were included. CT scan of carotid artery was done to all patients pre operatively. Patients were assessed using audiometry, tympanometry and pressure swallow test pre-operatively and after BET procedure (1 week and 6 weeks). All procedure was done under general anaesthesia.	II-3	Four patients (three had bilateral Eustachian tube dysfunction. Age range: 23 to 61 years.	Balloon Eustachian Tuboplasty	-	six weeks	**Eustachian Tube Score (Air bone Gap/ Tympanometry/ Pressure Swallow Test, PST).** A significant improvement in Eustachian Tube Score (reduce in air bone Gap, conversion to Type A tympanometry and significant improvement in PST.	

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