Short Summary of the 1st International and 5th National Symposium on the Balloon Eustachian Tuboplasty

Hamburg, Germany

June 24th 2015 5th National Symposium

June 25th to 26th 2015 1st International Symposium

Chairman: PD Dr. C. Dalchow,

Organization: Prof. M. Tisch, Prof. G. Lehnerdt, Prof. H. Sudhoff,

Venue: Hotel Atlantic Kempinski, Germany

SPIGGLE & THEIS
Medizintechnik

In cooperation with the Department of
Oto-Rhino-Laryngology, Head and Neck Surgery
University Medical Center Hamburg-Eppendorf

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AT:	Adenotomy
BET:	Balloon Eustachian Tuboplasty / Balloon dilatation of Eustachian Tube
CI:	Carotis Interna
COM:	Chronic Otitis Media
GERD:	Gastro Esophagus Reflux Disease / Reflux (esophagitis)
OME:	Otitis Media with Effusion
E:	Effusion
VT:	Vent Tube
ETD:	Eustachian Tube Dysfunction
TMM:	Tubomanometry

Introduction

Now, after five years of experience with balloon dilatation of the Eustachian Tube, Spiggle & Theis in cooperation with the University of Hamburg-Eppendorf organized the first ever International Symposium for the treatment of Chronic Eustachian Tube Dysfunction.

Renowned ENT surgeons from world-wide 19 countries met from the 24th to 26th of June 2015 in the Hotel Atlantic Kempinski Hamburg to exchange and present their experiences on the Balloon Dilatation of the Eustachian Tube.

Besides diagnostic methods, treatment of children and clinical indications, experiences of procedural challenges were debated and exchanged.

Initial results were shown for ongoing national and international studies. The symposium at the end of the day had shown that Eustachian Tuboplasty is an effective, quick and safe method to treat chronic Eustachian Tube Dysfunction and should continue to gain importance in the future.

As a summarization, the following issues were reported and discussed by the participants.

Basic Information

Functions of Tuba Eustachii

- Pressure Equalization
- Aeration of Middle Ear
- Protection from ascending microbes or in case of GERD (Gastroesophageal reflux disease)
- Drainage-Function for secretion

  Active opening of ET with Swallowing or Toynbee-Maneuver
  Passive opening after rising pressure in the Middle Ear area

Epidemiology

- Incidence in Adults: 0.9%
- Prevalence: 1 – 5 %
- Incidence in Children: about 40% in Children <10 Years

Consequences of ETD

- Pressure in the Ear, Under-Water-Feeling, Pressure in the Head
- Pain, impaired Hearing
- Serous or mucous OME (Otitis Media with Effusion)
- Chronic or recurrent OMM (otitis media mesotympanalis)
- Chronic Middle-Ear Adhesion-Process
- Epitympanic Cholesteatoma
- Conductive deafness (in early childhood→disorder of speech development)

Indications

Classic indications:

- ETD with recurrent Effusion **(E)**
- Epitympanic Retraction
- Persisting pressure feeling after conservative treatment
    - (e.g. Flight Attendants , Divers)

Special Cases: (former contra indications) Prof. Tisch

- Radiation-Patients with persisting Effusions
  (80% success rate)
- Cleft-Palate Patients (40% success-rate (small group))
- Adhesive-Process with partial removal of a tympanic blister
  (High success-rate (90%) in children)
  Adjacent Tympanic Membrane to the Ossicular Chain of more than 25% → BET is an alternative procedure to a relining of the Tympanon

- BET revision in case of non-responding (28 %) → Glue Tube-Theory
  Recommendation: removal of the balloon in an inflated modus

Diagnostic

Overview of Diagnostic in Eustachian Tube Function

- Valsalva
- Toynbee-Maneuver
- Imaging
    - Endoscopy
        - Pharyngeal, trans nasal 0-90°
    - Schüller X-Ray
    - CT, MRT, DVT is not being used very often
- Other options
    - Sonotubometry
    - Pressure Chamber
    - Electromyography
- TMM
  Usually clinical tests, Tympanometry und conventional Imaging is standard.
  Tubomanometry (TMM) is getting more and more popular, but is still not known to the majority of ENT-hospitals.

Remarks to Diagnostic of ETD

- Differentiation in diagnostic of ETD is requested :
    - situative **ETD** → e.g. Flight Attendants or Divers
    - chronic **ETD** → e.g. Patients with recurrent OME
- Cause for ETD might be found in the tympanal area or in the Nasopharynx
    - Intratubal Obstructions : Lymphatic Tissue, „GlueTube“,
    - Mucosa Swelling, Stenosis, Scars
- Thorough endoscopic examination pre- and post-operative before de-swelling claimed
- Experience : in 10% of **ETD**-Patients the cause may be found outside the Tube; therefore no isolated consideration of the Tube should be done
- **CT** before BET is not deemed mandatory, only in case of special indications, whereas recommended in Revision-BET´s
- In case of aberrant course of the carotid artery (Carotis Interna) **(CI) or** dehiscence (missing bony coverage of the carotid artery **CI**), a **CT** is recommended only in case of unclear anamnesis, because a dehiscence usually is not related to a critical area which is involved in dilatation of the Eustachian Tube
- Radiological Diagnostic is not necessary
- A „Golden Standard“ for ETD diagnostic does not exist
- Tubenmanometry (TMM) is efficient and produces good results
    - Reliability und Validity of TMM is checked and proven by Klinikum Bielefeld, Germany

- Confirmation in Esteve-Study; in about 20-25% no objective Measurement possible
- Misinterpretation through artefacts possible; cerumen may influence the measurement
- Tips for TMM : Measurement below 30mbar, Valsalva with TMM without nasal-adapter
- Negative Valsalva-Test significant; correlates good with TMM results
- Valsalva-Discrepancy detected: subjective result 88,8% improvement, objective 82,9%
- Possible Questionnaires : ETS-5 and ETS-7
    - ETS-5 not applicable when the Tympanon is intact; ETS-7 includes TMM-Result
- Tympanometry and the Assessment of the doctor should be taken into consideration
- Combination of more than one diagnostic procedures is required
- For evaluation of therapy results GBI (Glasgow Benefit Inventory) possible
- Publication from Military Hospital Ulm about Pressure-Values affirm the recommendations about **CT** (no risk out of BET-procedure to be expected)

Operation Procedures and Complications

Complications:

- About 10-12 Cases of Air-Emphysema after damaging the tubal mucosa has been reported
  In all cases healing in short-time without complications
- Very seldom „Falling“ of Middle Ear Prosthesis → longer waiting period before BET, Paracentesis

BET and Tympanoplastic in one Operation (Prof. Lehnerdt)

- Operation-Rule: Nose before Ear!? → Tube before Ear?
- Ear-Symptoms often consequence of ETD!
- Combined Operation Tymp/BET no disadvantage regarding costs, OR-Time and tympanic Closing-Rate
- Combined Operation BET/Adenotomy possible and of advantage
- Increase of Success-Rate with Valsalva-Training
- **TubaClean®** introduced as new Operation-Tool

BET in Children

Diagnostic in Children

- Ear-Anamnesis Child with Parents
- Otoscopy and Valsalva-Test
- Pure Tone Audiogram
- Impedance Audiometry
- Tubomanometry difficult with Children (see remarks)

Golden Standard

- Thorough Indication
- Anatomical Situation often more difficult than in Adults
- First usage of Privin and Cortino Nasal Sprays/gels
- Tubal Training/ Otovent
- Adenotomy with Paracentesis/VentTubes
- No success→ BET

Remarks to BET in Children

- Fear of Causing Damages to the carotid artery (Ateria carotis interna) in case of dehiscence of the canalis caroticus

- No objective risk (Tisch et. Al. 2013), because the pressure-value being used is by far not enough to cause a fracture of the bone at an average thickness of 0,97-1,06mm. Even with a thickness of 0,3 mm a damage seems to be very much unlikely
- Very often Mucous –Emission while removing the balloon
- Often improvement of clinical Ear-Symptoms and Tympanic-Situation as a result of BET
- On the contrary: often no improvement of the TMM-Result post-operative in Children TMM-Measurement generally difficult with Children
- Parents report of very high rate of subjective improvement in Children after BET
- Discussion about combined **AT** and BET

Conclusion to BET in Children

- BET is a safe, easy and quick treatment of chronic ETD in childhood
- Preoperative Diagnostic is easy and can be done in every clinic
- BET should always be done under general anesthesia, BET is possible as Day-Care Treatment as well as stationary
- About 80 % improvement of symptoms (subjective?) without any severe complications

Main clinics for BET Treatment in Children in Germany

- Military Hospital ULM
- Diakonissenkrankenhaus Karlsruhe
- St. Anna-Klinik Wuppertal
- Universitätsklinikum Hamburg-Eppendorf (UKE)
- Städtisches Klinikum Bielefeld
- Olgakrankenhaus Stuttgart
- Universitätsklinikum Lübeck
- Universitätsklinikum Marburg
- Universitätsklinikum Heidelberg

Revisions (BET):

- Not to be done after mistakes in indication
- Revisions make sense when problems occur in anatomical situation (correct handling not possible, as well as in relapse pathologies
    - (e.g. severe Adhesive-Processes)

Studies

- Not many studies available for TMM
- Introduction of a retrospective Multicenter-Study of **BET** in Children with chronic Effusion (Dr. Euteneuer)
    - 9 Clinics, 173 Children, 296 Ears (72% bilateral),
    - Follow-Up 164 (94,8%);
    - Results: 65,2 % normal compliance status (all problematic patients) ; unsatisfied 20%.
- Discussion, short time publication or waiting for next follow-up
    - The majority is favoring short time publication
- Prospective, randomized, double-blind Multi-Centre-Study in Germany to follow soon

Discussions

- Definition : „BET no Operation, but Intervention“ (Prof. Tisch)
  Objection: Phrase could weaken the argumentation with health authorities in discussion about reimbursement
- Earnings for the procedures are cut down by MDK`s (medical services of health insurance)
- Resistance against MDK requested, even judicial issues
  Argument: „**BET** is not listed in the catalogue for ambulant treatments “
- Complications in **BET** are to be documented and used as arguments in discussions with the health authorities
- TMM-documentation should be used to strengthen the argumentation
- Within the next 3-5 years a coding for BET as day-care treatment is to be expected (Contacts Prof. Tisch in Baden-Würtemberg)
- Consensus (-Paper) for acknowledgement as day-care treatment with adequate payment requested → coming soon

Tuba Aperta

Examination

An examination only makes sense, when symptoms are acute.

- Tympanon: grey, reflecting, sometimes retracted
- Movement in Tympanic Membrane in forced breathing
- Valsalva only helps for a short period of time
- Endoscopic examination shows the tubal orifice wide open, especially when breathing and swallowing
- Tympanometry shows typical curve congruent to breathing tympanic movement
- R-Parameter in TMM-report <1; wave-like curve

Therapy

Conservative

- Patient education
- Causative reasons: Weight-Stabilization, Diuretics etc.

Medication

- Nasal: Anticholinergics, LugolGel, Saline Solution, etc. → swelling of the tubal mucosa →temporary closure of Tube

Surgical

- Injection of active agents into torus tubarius e.g. Paraffin, Teflon, Gealfoam etc.
    - **Cave: cerebral Thrombosis with injection into the carotid artery**
    - Vox-Implant→Polydimethylsiloxane-Elastomer-Implant
- Autologous Fat-Tissue→ easy and without complications
- Paracentesis/VentTubes
    - Symptoms get better in 50% of cases
- Laser assisted curvature inversion technique (CIT)
- Patulous Eustachian Tube Reconstruction (PETR) (Poe)
- Kobayahi Plug (PEP)

New Procedure: TubaInject® / VoiceInject®

- **Fat-Tissue is an ideal filler because:**
  - Biocompatible
  - Easy to harvest
  - Long lasting
  - Transferred Fat Stem cells (ASC) may develop new Tissue
- **Harvesting**
  - Coleman-Liposuction with cannula, syringe and vacuum-pump
- **Transplant Preparation**
  - Separation of Fat-Ingredients with a centrifuge from blood or damaged fat cells
- **Injection**
  - Injection into tubal orifice with TubaInject®→ avoiding of voluminous Lipoinjection in order to avoid development of Cysts etc.

Postoperative Resorption up to 30 – 50% of the transplanted Fat-Tissue possible

International Meeting

- Some reports from different countries
  (Success-Rates partly lower than in Germany)
- Discussions and Exchange about points 1-6
- Requests for more Studies about BET, Publications about Long-Term Results, Guidelines including Definitions of Indications, Diagnostic and Success-Evaluation
- Discussion and exchange about special cases

Summary: Martin Koch, Spiggle & Theis Medizintechnik GmbH