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The cartilaginous Eustachian tube: Reliable CT measurement and impact of the length☆

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ABSTRACT

Purpose: Balloon dilation of the Eustachian tube is a treatment option for obstructive Eustachian tube dysfunction. The desired balloon position is in the cartilaginous portion. However, the balloon catheter may slide into the bony portion without the surgeon's knowledge. Knowing the length of the cartilaginous portion may improve catheter positioning, but there is no published research on measuring this portion selectively or on whether the length has an impact on development of disease or treatment outcome.

To evaluate whether a measurement obtained from CT images is valuable and accurate, to standardize the manner of which the length is measured, and to compare our radiologic measurements to procedural findings, we designed a combined study. Further, we tested the length's influence on development of disease and treatment outcome.

Methods: Anatomical end points of the cartilaginous part of the Eustachian tube were unambiguously defined. The length was retrospectively measured bilaterally in 29 CT examinations by two radiologists, and repeated by one after two weeks. New reformats and measurements were made after 18 months for 10 of the patients.

Prospectively 10 patients were included in a study where the length measured on CT was compared to per-procedural measurements based on catheter insertion depth to isthmus. Various parameters including length and treatment outcome were measured in 69 patients and 34 controls.

Results: Correlation was adequate to excellent in all comparisons. The length of the cartilaginous Eustachian tube did not predict treatment outcome or disease development. The lengths were significantly shorter in females.

Conclusion: Measuring the cartilaginous portion of the Eustachian tube on CT images is precise and reproducible, and reflects the length measured intraoperatively. However, it does not seem have a prognostic value.

1. Introduction

Ventilation problems due to Eustachian tube dysfunction are associated with several middle ear conditions. Until the present decade, tympanostomy tubes have been the only option to surgically improve middle ear ventilation.

During the present decade, balloon dilation of the Eustachian tube (ET) has evolved from pioneer testing with the first studies published during 2010 and 2011 [1–4] to a treatment option [5,6]. Even though it is debated, whether dilation in the bony part of the ET can damage vital structures like the carotid artery [7], complications have occurred with similar methods [8,9] and the desired balloon position is in the cartilaginous portion. The cartilaginous part of the ET is flexible, and therefore it is possible to expand a balloon catheter with a much larger diameter. The bony isthmus is the surgical limiting factor, and therefore an anatomical point of interest. However, there seems to be little focus on the significance of the cartilaginous ET's length, which is the target in balloon treatments. The length is known to vary considerably [6]. If

Abbreviations: CT, Computed tomography; ET, Eustachian tube; MDC, Minimal detectable change; MDCT, Multiple detector computed tomography; OME, Otitis media with effusion; SEM, Standard error of measurement

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it is known to the surgeon in advance, we argue that this will facilitate the choice of balloon length and provide information on how far the catheter needs to be inserted to reach the isthmus. A preoperative measurement can assist the optimization of catheter positioning and contribute to conduct a safe and predictable procedure.

In our hospital, all patients undergo a temporal bone CT to rule out other pathologies including obstruction in the bony portion of the ET before balloon treatment. Hence, if the length of the cartilaginous portion can be derived from the CT, more than one purpose can be served.

Sudo et al. measured the length of the cartilaginous portion using computer reconstructions of cadaver specimens [10], versus both Dinc et al. [11] and Takasaki et al. [12] who measured the ET as one unit without isolating the cartilaginous portion, which is the treatment target. However, we have not found studies on CT measurement of the cartilaginous portion. To include the full length of the cartilaginous portion in one reconstructed CT image, one must make oblique coronal reformats and have stable, visible reference points. Our goal was firstly to establish a simple and reproducible CT measuring method for the length of the cartilaginous portion of the ET, and to ensure the quality of the method. Secondly, we intended to examine whether the length has an impact on development of disease, the outcome of treatment and if length differs with gender and age.

2. Material and methods

2.1. CT measurement method

Retrospectively, we included all adult patients who were referred to CT of the temporal bone due to ET dysfunction in 2013. Twenty-nine patients were included, 19–79 years, mean age 48, median age 53, 13 female. In consensus, two radiologist and two otologists determined the cranial and caudal limits of the cartilaginous ET. The cranial limit was defined as the bony eminence at the medial side of the bony ET's caudal end. This eminence is formed by a thickening of the bone separating the carotid canal from the bony ET. The caudal limit was defined as the tip of the soft tissue lip of the torus tubarius on one, single CT image (Fig. 1). From the CT raw data, we made tilted coronal reformats projecting both points in the same image plane. Individually two experienced ENT radiologists measured the cartilaginous part of the left and right ET in each patient. One radiologist repeated the measurements after two weeks. All measurements were blinded to previous results. To examine whether the reformat procedure per se would influence the length measurement, we made new CT reformats and new measurements for ten of the patients after 18 months.

2.2. Comparison to catheter measurement

Prospectively, CT measurements were compared to the actual endoscopic findings. Ten patients (seven female, mean age 33 [median 35, range 23–56]) were included. Blinded for the CT measurements, the surgeons measured the length defined as the catheter insertion depth from the tip of the torus tubarius as the catheter met resistance. All endoscopic measurements were done with Acclarent Aera™ catheter (Acclarent Inc., Irvine, CA, USA). This balloon catheter was specifically designed for ET balloon dilation. The tip is rounded and has a diameter of 2.2 mm, which induces a resistance when it reaches the isthmus. Thus, we defined the depth of registered resistance to represent isthmus.

The balloon catheter was inserted until resistance was felt at the assumed isthmus. After balloon dilation, a guide catheter was placed to the tip of the torus tubarius. The whole catheter with emptied balloon and guide were simultaneously pulled out and the length of the disposed catheter was measured from the tip of the guide catheter to the tip of the balloon catheter.

Two patients were treated unilaterally, and subsequently the two contralateral CT-measurements were excluded, resulting in 18 included tube measurements. In this study, we regarded each side as independent.

2.3. Clinical measurements

All adult patients who had been treated with balloon dilation of the ET due to OME from February 2013 through June 2016, and had a preoperative CT of sufficient quality to make new reformats, were included. This resulted in 97 ETs in a total of 69 patients (40 female, mean age 45). In the preoperative CT of the temporal bone, the cartilaginous portion of the ET was measured using the CT measurement method. Both sides were measured regardless of whether disease was unilateral or bilateral, but ears with disease were registered separately. As controls, we included 34 (14 female, mean age 50) adult patients with temporal bone CT-examinations without history or findings of middle ear disease. The controls were retrospectively included from the CT examinations performed at our institution over the same time period as the patient group. We recorded gender, age at CT examination, and length of the cartilaginous portion of the ET in both groups, and treatment outcome and time between CT and surgery in the patient group. All patients had a clinical follow up 3 to 6 months after balloon dilation. Valsalva, position of the tympanic membrane and aeration of the ME were evaluated, and each given one point if normal, giving a scale from 0 to 3 points. 0 or 1 point was classified as a poor result, while 2 or 3 points as satisfactory.

The CT examinations in all three studies were conducted on a Toshiba Aquillion One, with 135 kV, 200 mA and 158 dFoV with a slice thickness of 0.67 mm. The tilted coronal reformats were 1/1 mm average intensity projection.

The studies were conducted according to the Helsinki declaration and approved by the National Ethics Committee and Oslo University Hospital's research authorities. Patients in the prospective study gave their informed consent to participate.

3. Statistics

Continuous variables are described as mean ± standard deviation. The Pearson correlation coefficient between measurements was calculated.

Difference between left and right cartilaginous ET was tested with paired Student's *t*-test. Inter- and intrarater reliability between CT measurements and internal consistency between CT and endoscopic measurements were tested with reliability tests, e.g. Bland-Altman plots and the intraclass correlation coefficient. Standard error of measurement (SEM) and minimal detectable change (MDC) were calculated as shown in eq. 1

$$MDC = 1.96 \times \sqrt{2} \times SEM \quad (1)$$

In the clinical measurements, both sides were measured in the same patient. These clustered data within the same patients was therefore assessed by using Generalized estimating equations with an unstructured working correlation matrix.

4. Results

Cartilaginous ET length as measured by CT was 26.8 ± 2.1 mm on the left side, 26.6 ± 2.0 on the right side and 26.7 ± 2.1 mm for all summarized measurements. The complete range was between 21.7 and 32.6 mm. There was no statistical significant difference between left and right side ($p = 0.32$). For measurement on similar CT sets, the Pearson correlation coefficient between measurements was 0.93 between observers and 0.92 for repeated measurements of one observer. Inter- and intrarater reliability between CT measurements was excellent with an intraclass correlation coefficient of 0.93 and 0.92. CT measurement of 20 cartilaginous ET lengths was repeated after renewed

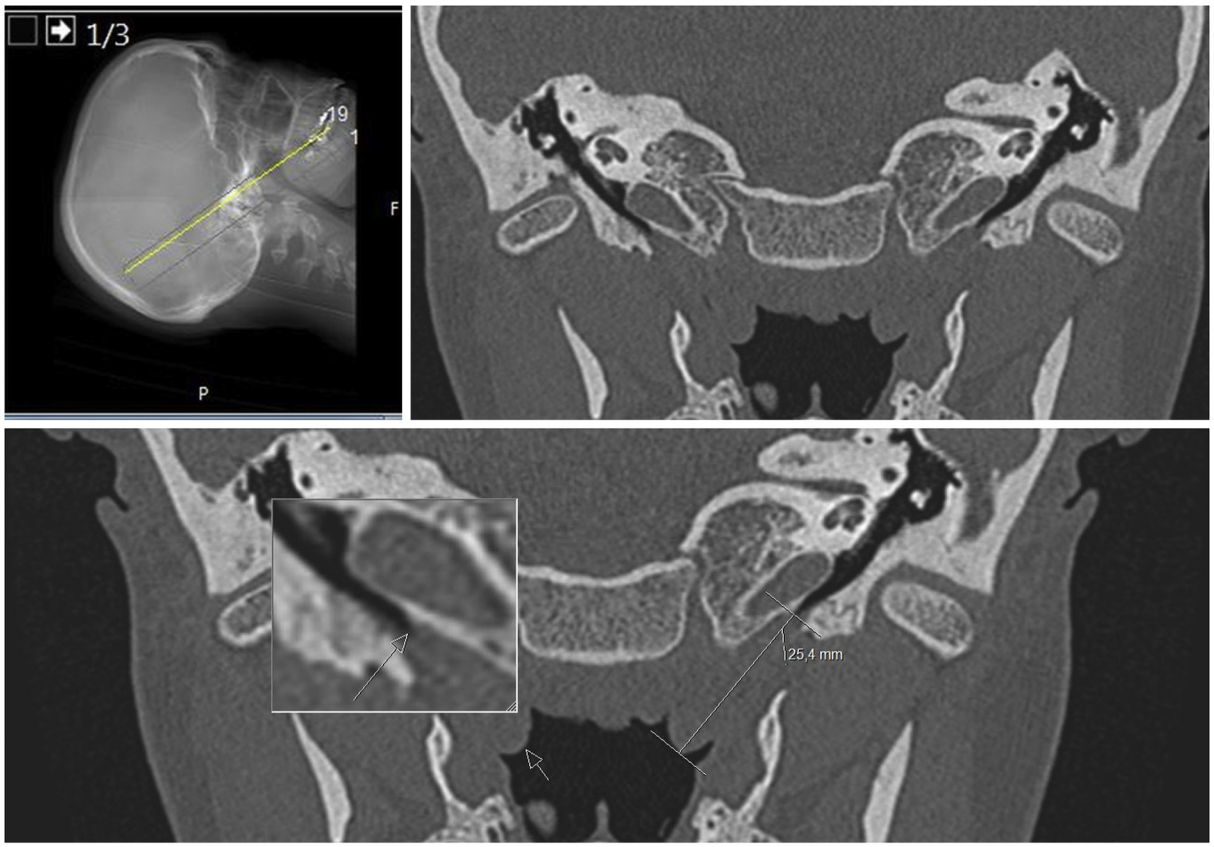

Fig. 1. Upper left: The angle and area of reformatting.
Upper right: The oblique coronal image plane from which measurements were made.
Bottom: Same image as above with magnification of the bony eminence at the caudal medial end of the bony ET (long arrow) and short arrow pointing to the tip of the torus lip. Measurement as it was made on the contralateral side.

tilted coronal reconstruction of the datasets in 10 patients and the Pearson correlation coefficient between measurements was 0.92. Interrater reliability after renewed reconstruction was excellent with an intraclass correlation coefficient of 0.92. Based on results from analyses before and after renewed dataset reconstruction, the SEM and MDC was estimated to 0.013 mm and 0.036 mm, respectively.

Cartilaginous ET length of the smaller sample was 26.2 ± 1.6 mm as measured by endoscopy and 26.0 ± 1.6 as measured by CT. The Pearson correlation coefficient between endoscopic and CT measurements was 0.64. The internal consistency between endoscopic and CT measurement was adequate with a Cronbach's alpha of 0.78.

A Bland Altman plot with a regression analysis revealed no bias dependent on cartilaginous ET length (Fig. 2).

The results for our clinical measurements are summed up in Table 1. We found that cartilaginous ET length was not predictive for development of disease or for treatment outcome. Females had shorter cartilaginous ET lengths. However, there was no correlation between gender and treatment result. Furthermore, no correlation was found between age and length or length and treatment outcome. Time between CT and balloon dilation did not influence treatment outcome. 7 of the 97 sick ears had a poor treatment outcome with a score of 0 or 1 of the possible 3 points. One patient had a poor result bilaterally, while the other five were treated unilaterally.

5. Discussion

We have developed a method to measure the length of the cartilaginous part of the ET on CT images, which is reproducible and comparable to endoscopic finings. The measurement can easily be obtained from the reformatted images acquired from the preoperative CT volume. Our measurements have excellent reproducibility both between observers on similar datasets and after repeated reformatting and measurements. Low MDC confirmed high measurement precision. CT measurement accuracy, especially in 2D, is generally considered high. Although measurement may be influenced by the image plane selected, physical image settings and signal-to-noise ratio, it has been shown that measurements are comparable [13]. For increased relevance, we chose to perform this study on routine temporal bone CT examinations originally not planned for cartilaginous ET length measurement. All examinations had axial high-resolution image stacks with slice thickness of 1 mm or less. In this setting, signal-to-noise ratio is high, measuring the interface between bone and soft tissue cranially and soft tissue and air caudally. In the lack of any measurement gold standard, we compared to endoscopic measurement. For this comparison, precision was reduced. Potential explanations are the complexity of the manual procedure for endoscopic measurement, that resistance of the catheter tip of 2.2 mm is not necessarily met at the point measured, and that the torus tubarius protrusion and epipharyngeal mucous membrane thickness might have changed between CT examination and endoscopy. Given these sources of error, an adequate reproducibility is considered fair. There was a mean difference of 0.00 mm between the methods, suggesting that accuracy of the measurements is good.

Any anatomical measurement is dependent on a precise, unambiguous definition. Although the temporal bone is anatomically complex, the definition in this study served the purpose of a measurement with excellent reproducibility, even though repeat measurements were dependent on sufficiently precise repeat reformatting. We chose to define the caudal ET end at the torus tubarius to strengthen reproducibility in an area of soft tissue with little contrast on CT images. Our study shows a good correlation between the catheter insertion depth

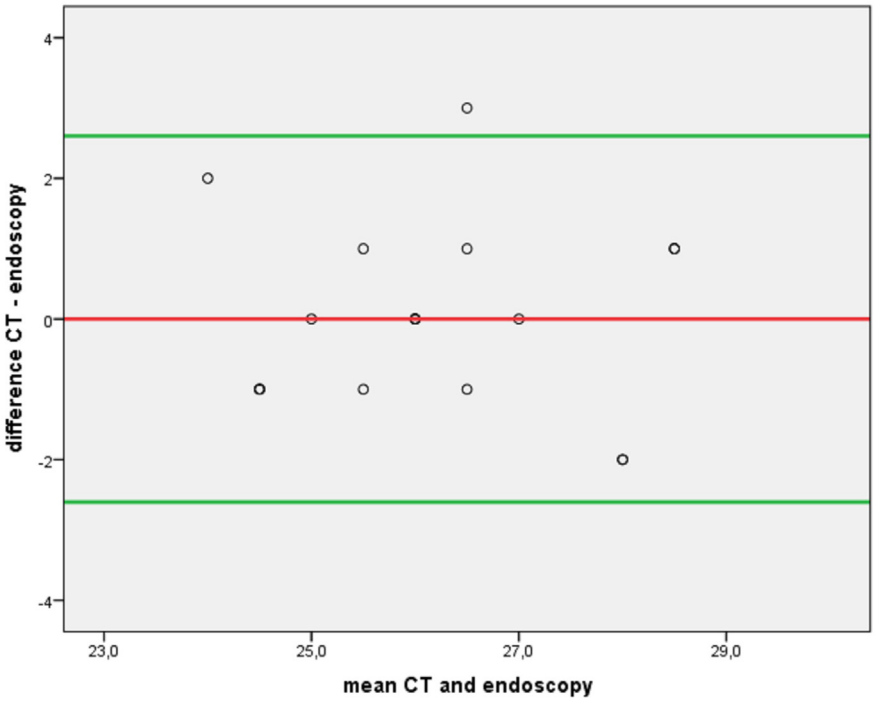

Fig. 2. Bland Altman plot on difference versus mean of CT and endoscopic measurements of ET length, measurements in mm. Mean difference is 0.00 mm (read line), green lines define ± 1.96 SD. Regression analysis confirms mean difference is not dependent of mean ($\beta = -0.31$, $p = 0.90$). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Table 1
Number of ETs and the corresponding mean length, mean difference and *P* value in each comparrison.

Problem	# ETs	Mean in mm	Mean difference	*P* value
Length vs. outcome	90 good	27.4	−0.11	0.482
	7 poor	26.9		
Length in ears with OME vs. control gr	97 OME	26.8	−0.53	0.266
	68 control	26.4		
Length in patient gr vs. control gr	138 patient[a]	26.8	−0.44	0.349
	68 control	26.4		
Length vs. age	206 all	26.7	0.01	0.270
Length vs. gender	108 female	25.8	−1.88	0.000
	98 male	27.7		
Outcome vs. age	90 good	27.4	0.01	0.637
	7 poor	26.9		
Outcome vs. gender	90 good	27.4	−1.69	0.128
	7 poor	26.9		
Outcome vs. short tubes 5 mm	90 good	27.4		0.084
	7 poor	26.9		
Outcome vs. timespan between CT and op.	90 good	27.4	−0.01	0.817
	7 poor	26.9		

[a] The healthy ears in the patient group are included.

and CT measurements, despite the findings of Sudo et al. [10] where the narrowest point of the ET was found to be within the cartilaginous portion, and not at the junction between bone and cartilage, when measuring on human cadaver specimens. One may speculate that the narrowest point found in Sudo's study is in fact more flexible than the junctional portion in vivo. The fact that the cartilaginous ET is slightly curved and that our measurement is slightly off axis of the true ET lumen also seem to have little influence on measurements. The balloon catheter probably straightens the cartilaginous ET. As opposed to the work of Takasaki et al., we have only measured the cartilaginous portion of the ET, as this is the target area for balloon treatment. We also chose the soft-tissue tip of the torus as an endpoint. It can be argued that the volume of the soft tissue in this area may vary both between individuals, but also with time and immune status within the same individual, hence influencing the measurement. On the other hand, the torus is a structure, which is easy to distinguish, given there is no epipharyngeal mass or previous major epipharyngeal surgery.

We did not adjust for smoking in the statistical analysis, as we did not possess such data. Nevertheless one can assume that most patients maintained their smoking habits over the given timespan, and therefore the comparisons made between the radiologic and endoscopic measurements should be uninfluenced on an individual level.

There is a certain bias in measuring both sides in the same patient, as the first length will create an expectancy of the contralateral length; however, we chose to ignore this in the first study. In the second study, we found it more appropriate to address this, as the measurements were compared to other factors.

As a method to determine the level of dysfunction has yet to be established [14], the current standard is to insert the balloon catheter to the isthmus, regardless of the length of the cartilaginous portion. The catheter we used should stop at isthmus level. However, as any other anatomical structure, the diameter of the isthmus may vary individually, and all catheters may unintentionally be inserted beyond the isthmus. Regardless of whether inflating the balloon within the bony portion is associated with a risk of complications or not, it is the cartilaginous ET that is the area intended to treat and where results have been documented. Knowing the length of the cartilaginous portion of the ET in advance, may contribute to obtaining the catheter position intended.

Although some variance between machines and algorithms can be expected, we believe the method to be fast and transferrable to any MDCT-volume that includes the middle ear and the torus lip. Thus, it can be used anywhere and be a basis for future studies where the cartilaginous ET length is a factor. The measurement itself can assist the surgeon both in the choice of catheter length and in the positioning of the balloon.

We did not find that the length of the cartilaginous ET influences disease development or treatment outcome, and the scale we used to score treatment outcome is not validated. However, the scale was based on common clinical parameters used for the evaluation of outcome, and should therefore reflect clinical relevance.

Females had significantly shorter cartilaginous portions of the ET. The explanation is likely physiological, however, knowing this the surgeon can adjust the insertion depth. As the length of the cartilaginous ET treatment appears to be independent of outcome, development

of disease and age, it remains to be seen whether other factors influence treatment outcome and can be used in patient selection.

6. Conclusion

The length of the cartilaginous portion of the ET can easily be obtained on CT images, and is reproducible and representative for the insertion depth to the isthmus with a balloon catheter. The cartilaginous ET is longer in men. Development of disease and treatment outcome seems to be independent of the length.

The above described studies were approved by the Institutional Board of Ethics.

The authors have no competing interests.

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