

Original Article

Chronic Otitis Media with Granulation Is a Poor Prognostic Factor for Hearing Improvement and Development of Intracranial Complications

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Cite this article as: Wiatr M, Składzień J, Stręk P, Przeklasa-Muszyńska A, Wiatr A. Chronic Otitis Media with Granulation Is a Poor Prognostic Factor for Hearing Improvement and Development of Intracranial Complications. J Int Adv Otol 2019; 15(1): 12-7.

OBJECTIVES: Different types of chronic otitis media are distinguished based on the observed lesions in the middle ear mucous. Hearing improvement is a measurable effect of the surgical treatment of patients with chronic otitis media. Chronic cholesteatoma otitis media and chronic otitis media with inflammatory granulation have a tendency to damage the bone tissue, leading to the development of intratemporal and intracranial complications.

MATERIALS and METHODS: A prospective analysis of patients who underwent surgery for the first time due to chronic otitis media from 2009 to 2012 was performed. Patients were divided into groups according to the abnormalities of the middle ear mucous observed during otosurgery. Special attention was given to patients diagnosed with chronic otitis media with inflammatory granulation and chronic cholesteatoma otitis media, which are characterized by a tendency to damage the bone tissue.

RESULTS: A total of 293 individuals met the criteria for inclusion in the study. The analysis showed that chronic otitis media with inflammatory granulation had an unfavorable effect on hearing improvement prognosticated postoperatively. Defects in the middle cranial fossa were observed to occur five times more often than defects in the posterior cranial fossa. These defects were usually observed with granulation tissue and rarely with the concurrence of cholesteatoma and granulation tissue.

CONCLUSION: The presence of granulation tissue is an unfavorable prognostic factor for improvement in air and bone conduction. The probability of exposing the dura mater of the brain is higher in cases with granulation tissue than in cases with cholesteatoma.

KEYWORDS: Otitis media, tympanoplasty, skull base

INTRODUCTION

The middle ear is a hollow space in the temporal bone consisting of the tympanic cavity, air cells of the mastoid process, and section of the auditory tube closer to the tympanic cavity with bony walls. Pathological processes, and in particular inflammatory conditions, are observed in these cavities. The treatment of acute otitis media is non-invasive, and surgery is performed only when the patient develops complications. Chronic otitis media (*otitis media chronica*) is characterized by a defect in the tympanic membrane, permanent or occasional discharge from the ear, and hearing impairment, either conductive or combined (where the perceptive component is also involved).

Different types of chronic otitis media are distinguished based on the observed lesions in the middle ear mucosa, namely, simple chronic otitis media, chronic otitis media with inflammatory granulation, chronic cholesteatoma otitis media, and chronic otitis media accompanying a specific disease ^[1, 2].

Surgery is the treatment of choice for chronic otitis media. A measurable outcome of the surgical treatment of patients with chronic otitis media is hearing improvement. The degree of hearing improvement corresponds to the closure of the air–bone gap (ABG),

This study was presented at the “XII. Zjazd Otolaryngologów Wojskowych”, “23–25 March 2017”, “Serock, Poland”.

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Submitted: 04.11.2017 • **Revision Received:** 16.11.2018 • **Accepted:** 07.01.2019 • **Available Online Date:** 15.03.2019
Available online at www.advancedotology.org



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i.e., the audiometric increase in the value of air conduction (where air conduction reflects the function of the sound-conducting system in the middle ear) compared with bone conduction [3,4].

In recent years, particular emphasis has been placed on protecting the ear from water through the preservation of the upper posterior wall of the external auditory meatus (referred to as canal wall-up tympanoplasty) or attempts at its reconstruction.

Chronic cholesteatoma otitis media and *chronic otitis media with inflammatory granulation* have a tendency to damage the bone tissue (ossicular chain and/or bony walls of the middle ear spaces). The destruction of bony elements affects the ossicular chain and often lowers the success of surgical treatment with regard to hearing improvement, whereas defects in the region of the temporal bone trigger the development of both intratemporal and intracranial complications. Inflammatory lesions of the bone tissue of the temporal bone and arterial thrombosis are two other ways where intracranial complications develop [5].

The aim of the present study was to define the type of mucous lesions that affect hearing improvement in patients who underwent surgery for chronic otitis media from the perspective of the closure of the ABG (air bone-gap) and the change in bone conduction after surgery. Furthermore, the type of chronic changes in the mucous and the resultant areas where intracranial complications may develop due to *chronic otitis media* was explored.

MATERIALS AND METHODS

A prospective analysis of patients who underwent surgery for the first time for chronic otitis media between 2009 and 2012 was conducted. A total of 457 patients underwent otosurgery during the time of analysis. Of the 457 patients, 134 had otosclerosis, 293 required surgery for chronic otitis media, and the remaining cases underwent surgical treatment of the middle ear due to tumor, damage, or an inborn defect of the ear. Table 1 shows the 151 successive patients with myringoplasty and 142 patients in whom ossiculoplasty had been performed who met the criteria for inclusion in the analysis.

Table 1. Characteristics of analyzed patients with chronic otitis media

Group no.	No. of patients	Characteristics of patients who underwent surgery
Patients with myringoplasty depending on the type of observed abnormalities (151 patients)		
1	24	Control group—myringoplasty, w/o discharge, normal mucous in the region of the middle ear (dry perforation)
2	27	Myringoplasty, w/o ossiculoplasty, w/o discharge in medical history but with abnormal mucous
3	38	Myringoplasty, w/o ossiculoplasty, with discharge in medical history
4	34	Myringoplasty, w/o ossiculoplasty, adhesions in the region of the middle ear
5	28	Myringoplasty, w/o ossiculoplasty, granulation tissue in the region of the middle ear
Patients with ossiculoplasty (142 patients)		
6	24	Ossiculoplasty, remodeled own ossicle (malleus or incus) placed on intact stapes; cholesteatoma
7	22	Ossiculoplasty, remodeled own ossicle (malleus or incus) placed on intact stapes; granulation
8	32	Ossiculoplasty, tympanic membrane graft placed on normal stapes
9	38	Ossiculoplasty, tympanic membrane graft onto the plate of the stapes (a palisade of cartilage strips between the plate of the stapes and the tympanic membrane graft)
10	26	Ossiculoplasty, partial ossicular replacement prosthesis placed on intact stapes

The study group comprised 160 women and 133 men. Of the 293 patients, the youngest was 22 years old, and the oldest was 66 years old. The average age was 43.96 years. Surgery was performed using the endaural approach in 58.33 % of the cases, and the retroauricular approach was used in 41.67 % of the cases.

Patients were divided into two groups: those in whom treatment involved only myringoplasty and those in whom the reconstruction of the ossicular chain was also required. These two groups were further subdivided based on the abnormalities of the middle ear mucosa identified during surgery. Hearing testing was performed immediately before surgery and 6 and 12 months after otosurgery.

Changes in the ABG and bone conduction were analyzed and expressed as the average values for frequencies of speech (500, 1000, and 2000 Hz). Special attention was given to patients diagnosed with *chronic cholesteatoma otitis media* and *chronic otitis media with inflammatory granulation*, which are characterized by a tendency to damage the bone tissue.

Statistical Analysis

The "Statistica" software (ANOVA; Statistica, StatSoft, Krakow, Poland) was used for statistical analysis. The multifield contingency tables for patients with chronic otitis media were taken into consideration, and the chi-square value was determined. The power of relationship was measured using the Cramer ratio. This test was confirmed using the chi-square NW ratio. A $p < 0.05$ was considered to be statistically significant. While interpreting the observations, the results referred to all patients with chronic otitis media who underwent surgery within the time span of the analysis.

RESULTS

The long-term results of the surgery were assessed by the change in the average bone conduction values between the groups. The assessment was made prior to the start of treatment (time 0) and after 6 and 12 months of follow-up. An ANOVA of the results over time revealed that the observed change of the average value of ABG within each of the groups after 6 and 12 months of follow-up was significant.

Table 2. Average ABGs observed within established groups before surgery and after 6 and 12 months of follow-up

Time (months)	X gr. 1	SD gr. 1	X gr. 2	SD gr. 2	X gr. 3	SD gr. 3	X gr. 4	SD gr. 4	X gr. 5	SD gr. 5
0	24.77	13.96	27.61	13.24	25.00	11.76	27.30	11.62	25.12	12.48
6	20.69	9.94	20.80	12.03	20.48	9.14	19.21	8.54	19.88	12.98
12	17.83	11.64	19.74	12.37	18.02	9.76	20.49	10.22	16.90	10.04
Time (months)	X gr. 6	SD gr. 6	X gr. 7	SD gr. 7	X gr. 8	SD gr. 8	X gr. 9	SD gr. 9	X gr. 10	SD gr. 10
0	31.87	10.58	27.35	9.37	32.08	10.32	38.68	10.36	33.28	11.25
6	19.79	6.23	26.51	10.79	26.77	10.76	35.26	9.77	25.98	6.83
12	19.31	7.33	27.35	12.63	25.10	10.99	35.44	14.35	25.33	7.39

The following abbreviations were used in the study:

X gr. "i" the average ABG in group "i,"

where "i" stands for number of the analyzed group (1–10)

SD gr. "i" standard deviation in the average ABG in group "i,"

where "i" stands for number of the analyzed group (1–10)

Statistically significant changes of the average value of ABG are in red (p<0.05).

Table 3. The average values of bone conduction in established group on the day of the surgery and at 6 and 12 months after surgery

Time (months)	X gr. 1	SD gr. 1	X gr. 2	SD gr. 2	X gr. 3	SD gr. 3	X gr. 4	SD gr. 4	X gr. 5	SD gr. 5
0	28.54	12.72	27.43	15.36	23.50	11.20	25.63	16.72	21.19	7.88
6	18.40	11.94	20.80	14.26	16.97	10.31	23.13	14.79	16.19	7.29
12	20.69	11.37	20.86	11.28	18.11	10.62	22.35	13.89	15.71	6.53
Time (months)	X gr. 6	SD gr. 6	X gr. 7	SD gr. 7	X gr. 8	SD gr. 8	X gr. 9	SD gr. 9	X gr. 10	SD gr. 10
0	27.57	19.07	30.07	13.80	34.58	19.03	25.35	10.97	29.74	13.14
6	26.74	17.30	24.77	12.37	34.27	16.87	23.42	13.09	29.74	14.43
12	26.04	16.61	26.43	13.93	35.62	16.59	23.59	12.43	25.25	14.16

The following abbreviations were used:

X gr. "i" the average value of bone conduction in group "i"

where "i" stands for number of the analyzed group (1–10)

SD gr. "i" standard deviation of the average value of bone conduction in group "i" where "i" stands for number of the analyzed group (1–10)

Statistically significant changes of the average value of ABG are in red (p<0.05).

The behavior of the average value of the cochlear reserve (ABG) within the particular groups was assessed (Table 2).

Based on successive hearing quality tests in patients who had undergone otosurgery, which consisted of an ANOVA of the obtained results over time, we assessed whether the observed change of the average value of bone conduction within each of the groups after 6 and 12 months of follow-up was significant. We also analyzed the average value of bone conduction within each group (Table 3).

In some patients, the bone defect of the middle or posterior cranial fossa was described and detected incidentally during the planned otosurgery in patients who had not been diagnosed with possible otogenic intracranial complications (Figure 1). In the remaining group of patients, middle ear surgery was a planned procedure to eliminate the source of infection and reconstruct the bony walls of the middle ear space. These latter patients had symptoms suggesting intracranial complications resulting from a pathological process in the middle ear.

Defects of the bony structures of the temporal bone in the base of the middle and/or posterior cranial fossa were usually asymptomatic. Most of the defects (80% to 90%) were revealed by accident during

the course of middle ear surgery. This highlights the importance of medical imaging, especially computer-assisted tomography of the temporal bone, during preoperative diagnostics (Figure 2). The ratio of patients with defects to those diagnosed with intracranial complications was estimated to be 10:1. These patients had not undergone earlier operations on the organs in question, and these structures had not sustained injuries (Figure 3).

The frequency of bony wall defects in the facial nerve canal or the fistula in the horizontal semicircular canal was comparable with the frequency of intracranial complications and was <20%. Facial nerve paralysis was not observed in any of the patients. Meningitis was most often reported, whereas meningoencephalocele or cerebral abscess was not as frequently reported. Other types of complications were observed in individual cases.

Defects to the skull base were observed more frequently in patients with *chronic otitis media with inflammatory granulation* than in those with cholesteatoma. However, abnormalities of the mucosa of the middle ear were not observed during surgery in 25% of the patients. Alternatively, lack of bone at the skull base that was either congenital or posttraumatic was present, even though such a condition had not been considered in the patient's medical history (Figure 4).

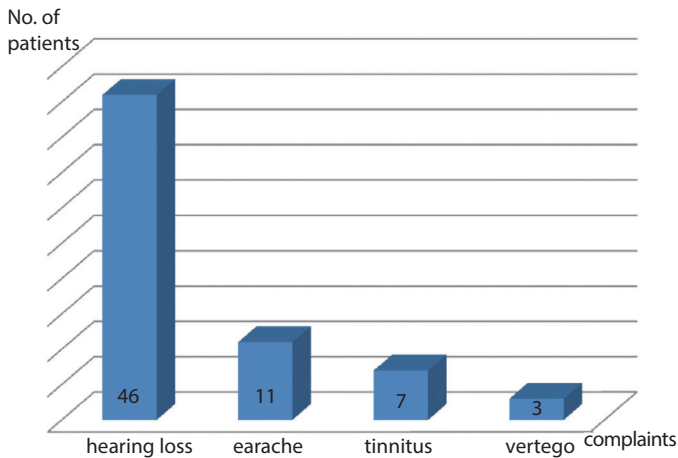


Figure 1. Patients with skull base defects before otosurgery.

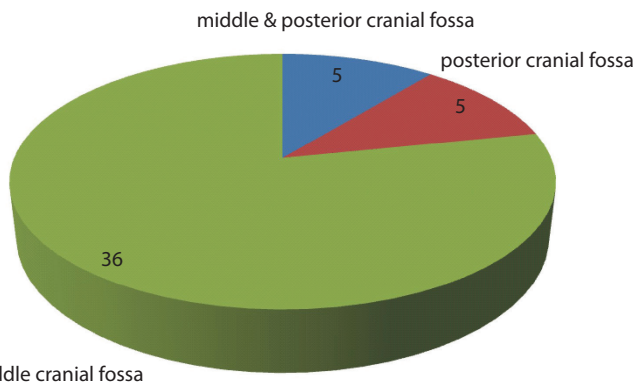


Figure 2. Localization of skull bone defects in the middle ear.

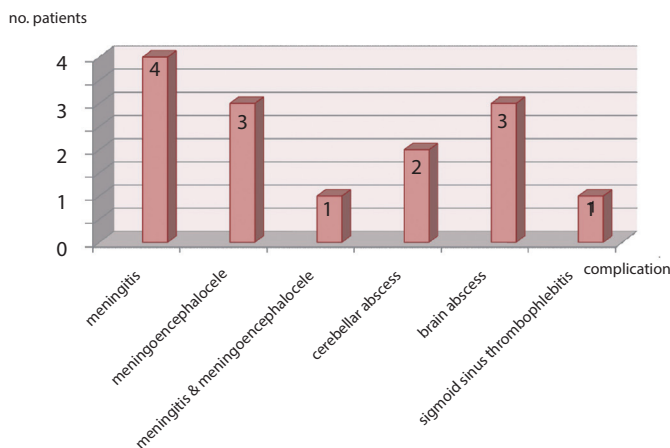


Figure 3. Observed intracranial complications in patients with chronic otitis media.

In the analyzed material, intracranial otogenic complications were observed in 1.3% of all cases of surgical treatment of the middle ear. Such complications occurred mostly in cases with *chronic cholesteatoma otitis media* and much less frequently in patients with *chronic otitis media with inflammatory granulation*. In patients with skull base defects resulting from inflammatory changes secondary to chronic otitis, all middle ear regions were usually affected, which was reflected in the scale of damage to the ossicular chain. Damage to all the

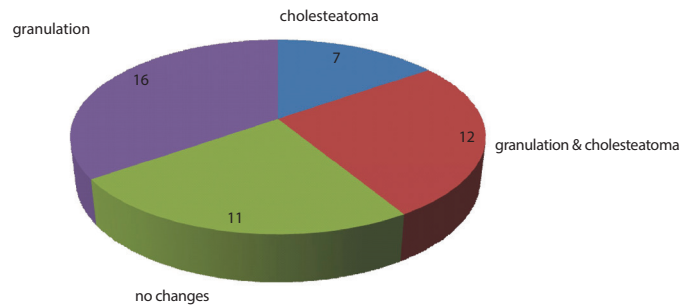


Figure 4. Changes to the middle ear mucous in patients with skull base defects.

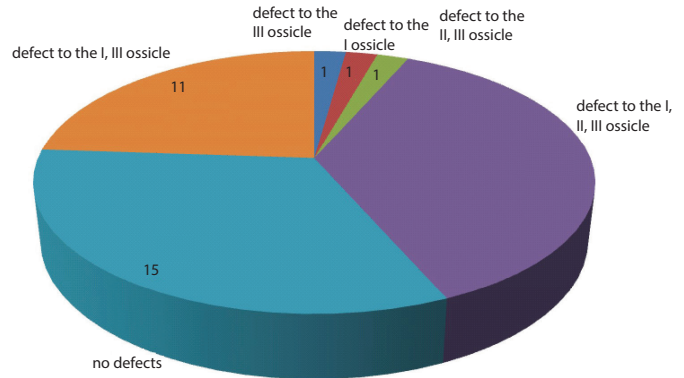


Figure 5. Defects to the ossicular chain in patients with skull base defects.

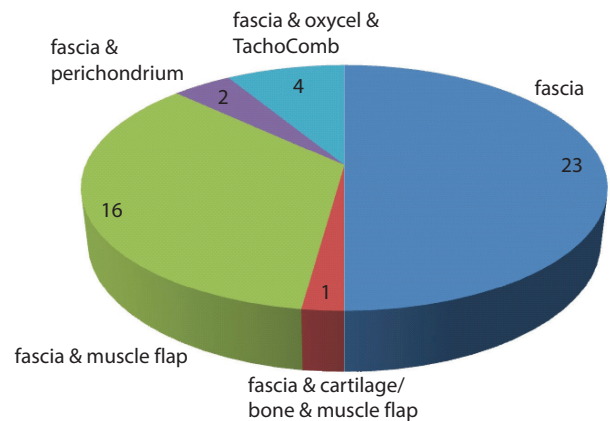


Figure 6. Performed skull base reconstruction.

ossicles was observed more often, whereas the concurrent destruction of the malleus and the incus was seen less frequently (Figure 5).

Restoration of the continuity of the walls of the middle ear during ossiculoplasty was effectively accomplished with surgical reconstruction of skull base defects (Figure 6). Regardless of the surgical treatment, routine non-invasive treatment was provided postoperatively, including administration of antibiotics (empirically and subsequently according to antibiogram) that penetrate into the cerebrospinal fluid and medications that lower intracranial pressure (mannitol and steroids) [6,7].

DISCUSSION

Our results show that *chronic otitis media with inflammatory granulation* has an unfavorable effect on hearing improvement prognosticat-

ed postoperatively in patients with a preserved ossicular chain. The key negative factors appear to be intraoperative bleeding, hypertrophic lesions of the mucosa, a tendency for adhesions, and impaired airtightness of the postoperative cavity through the auditory tube. In the remaining groups with myringoplasty, postoperative hearing quality was normal if there were preservation of the completely undamaged ossicles, normal mobility, and effective closure of the tympanic membrane gap [1-3].

Despite the reconstruction, damage to the ossicular chain brings about varying degrees of postoperative hearing impairment. The degree of impairment is a function of the dysfunction resulting from damage. Therefore, the hearing level after otosurgery must always be analyzed from the perspective of the reconstruction of the ossicular chain. It is often the case that the patient's hearing is more impaired after surgery than what it was before. This is because according to the method used during otosurgery, the primary aim is to remove the lesions, and it is only afterwards that the ossicular chain is reconstructed based on the sound-conducting elements preserved in the middle ear [8, 9].

Our research shows the importance of preserving the undamaged and normally movable stapes for improvement in hearing quality. A method of reconstruction that places either the modeled ossicle or part of the temporal bone, or a partial ossicular replacement prosthesis, on the head of the stapes results in postoperative hearing improvement. In the study patients, the improvement was significantly better in the group with cholesteatoma ($p=0.009$) than in those with concurrent *chronic otitis media with inflammatory granulation* ($p=0.96$), despite similar damage to the ossicular chain and the same type of reconstruction. In these cases, the occurrence of granulation tissue of inflammatory origin (*chronic otitis media with inflammatory granulation*) did not prognosticate permanent hearing improvement.

In comparable cases of reconstruction of the sound-conducting system in the middle ear, the range of ossicular chain damage and the type of changes to the middle ear mucosa determine the results of otosurgery with regard to hearing improvement. The hearing tests performed prior to surgery occasionally reveal the impact of the lesions (e.g., due to cholesteatoma) on the transmission of sound into the oval window. Therefore, the size of the ABG before otosurgery often does not reflect the actual stage of development of the pathological process and cannot be used as the only basis for prognostication of postoperative hearing improvement [10-12].

The analysis of the changes in postoperative hearing level shows the change in the course of the bone conduction threshold curve, which reflects the function of the sensory nervous part of the ear and is determined by the effect of the sound-conducting mechanism in the middle ear on the function of the inner ear.

The pathological process occurring in the middle ear appears to affect inner ear function by damaging ossicular chain mechanics. This is particularly significant in patients with lesions of the mucosa of the middle ear, such as advanced cholesteatoma, as well as when damage to the ossicular chain occurs.

The bone conduction disorder is also determined by the toxic effect of inflammatory mediators in the middle ear that affect inner ear function. Substances penetrating from the middle ear into the inner ear through the round window cause biochemical changes in perilymph and endo-

lymph. Only the preserved and fully functional ossicular chain has a favorable impact on inner ear function. Improved bone conduction was observed after effective myringoplasty, including in patients with *chronic otitis media with inflammatory granulation*. Surgery in the latter group not only removed abnormalities of the mucosa but also eliminated the toxic effect of inflammatory mediators on inner ear function [13-15].

Our analysis of patients who underwent surgery shows the lack of significant improvement in bone conduction post-surgery in patients with tympanic cavity adhesions. This may result from restricted mobility of the ossicular chain due to even partial recurrence of adhesions after surgery. We also observed that the lesions in the region of the round window have an unfavorable effect on bone conduction.

All abnormalities of the ossicular chain result in a lack of significant bone conduction improvement after otosurgery.

Middle cranial fossa defects were five times as common as posterior cranial fossa defects. Furthermore, the former present concurrently in the middle and posterior cranial fossae. *Chronic cholesteatoma otitis media* is associated with a lesser extent with exposure of the dura mater of the skull base. In the analyzed material, isolated cholesteatoma-related lesions were found in 15% of the patients who underwent surgery. The concurrence of cholesteatoma and inflammatory granulation tissue was more frequent. Patients with granulation tissue more often complained of earache [16].

Meningoencephalocele was observed in approximately 10% of patients with bone defects in the base of the middle cranial fossa. We found no cases of meningoencephalocele in the posterior cranial fossa. The infrequent defects in the posterior cranial fossa account for the less frequent occurrence of cerebellar abscesses, a type of complication characteristic of acute otitis or purulent hematoma, and usually observed in children.

CONCLUSION

The following conclusions can be drawn from the present study:

1. The presence of inflammatory granulation is an unfavorable prognostic factor for improved air and bone conduction.
2. The probability of exposure of the dura mater of the brain is higher in cases with inflammatory granulation than in cases with cholesteatoma.

Ethics Committee Approval: Ethics committee approval was received for this study from the Bioethics Committee of Jagiellonian University (no.122.6120.206.2016)

Informed Consent: The informed consent was taken from each patient included to the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – M.W., A.W.; Design – M.W., A.W., J.S.; Supervision – M.W., A.W.; Resource – M.W.; Materials – M.W., A.W., A.P.M.; Data Collection and/or Processing – M.W., A.W., A.P.M., P.; Analysis and/or Interpretation – M.W., A.W., J.S.; Literature Search – A.P.M., P.S.; Writing – M.W., A.W.; Critical Reviews – M.W.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: This research was supported by statutory funds of the Department of Otolaryngology of the Jagiellonian University, Krakow, Poland.

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