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Postoperative surgical site infection in cholesteatoma surgery with and without mastoid obliteration, what can we learn?

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A B S T R A C T

Introduction: This study aims to describe the occurrence of postoperative complications related to cholesteatoma surgery and to determine factors influencing the most common complication, i.e. postoperative surgical site infection (SSI) in cases with and without mastoid obliteration.
Materials and methods: Retrospective analyses were performed on surgically treated cholesteatomas in our hospital between 2013 and 2019. Patient characteristics, peri- and postoperative management and complications were reviewed. The cases were divided into two groups based on whether mastoid obliteration was performed or not.
Results: A total of 336 cholesteatoma operations were performed, of which 248 cases received mastoid obliteration. In total 21 complications were observed, of which SSI was the most common (15/21). No difference in occurrence of any postoperative complication was seen between the obliteration and no-obliteration group ($p = 0.798$), especially not in the number of SSI ($p = 0.520$). Perioperative and/or postoperative prophylactic antibiotics were not associated to the development of an SSI in both groups. In the no-obliteration group a younger age ($p = 0.015$), as well as primary surgery ($p = 0.022$) increased the risk for SSI. In the obliteration group the use of bioactive glass (BAG) S53P4 was identified as independent predictor of SSI ($p = 0.008$, OR 5.940).
Discussion: SSI is the most common postoperative complication in cholesteatoma surgery. The causes of SSI are multifactorial, therefore further prospective research is needed to answer which factors can prevent the development of an SSI in cholesteatoma surgery.

1. Introduction

Cholesteatoma is an ingrowth of squamous epithelium in the middle ear and/or mastoid with accumulation of keratin, resulting in a lesion that is destructive to its adjacent structures (Yung, 2017). The etiopathogenesis of acquired cholesteatoma is still not elucidated. A mix of mechanisms, combined with chronic inflammation, is considered to be crucial in its development (Persaud, 2007; Kuo, 2014). The primary goals of cholesteatoma surgery are to create a safe ear by complete eradication of the disease and to prevent recurrence and complications. Secondary goals are to optimize the hygienic status of the ear and to improve or preserve hearing. The choice of surgical technique is based on the preference of the surgeon, extension of the disease, anatomy, status of the ossicular chain and previous surgery. Mostly used surgical techniques are the canal wall down (CWD) and canal wall up (CWU). Nowadays, both techniques are often combined with obliteration of the mastoid and epitympanic space. The aim of obliteration is to decrease the risk of recurrent cholesteatoma. This is induced by preventing the tympanic membrane to retract in an open mastoid space, by reducing the mucosal surface for gas exchange and by creation of an unfavorable environment for the growth of residual cholesteatoma (Csakanyi, 2014; Hinohira, 1998). There are two types of material used for mastoid obliteration: biological and synthetic (such as bioactive glass (BAG) and hydroxyapatite (HA)).

In literature commonly described complications of cholesteatoma surgery are postoperative surgical side infection (SSI), postoperative pain, facial nerve palsy, deafness, vertigo, loss of taste, retroauricular hypertrophic scarring and granulation tissue in

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the external ear canal. Specific complications in the case of obliteration are infection due to filling of the mastoid with non-vascularized, sometimes foreign body material, and rejection of this obliteration material. Several authors mention complications of cholesteatoma surgery (Gantz, 2005; Kang, 2009; Kao, 2017; Van der Toom, 2018). However, to our knowledge, no dedicated report has previously been published on complications of cholesteatoma surgery with mastoid obliteration compared to conventional mastoid surgery.

This retrospective study describes the complication rate of cholesteatoma surgery during a 6-year period since the introduction of the mastoid obliteration technique in our hospital. We examined the clinical data to report on the occurrence of complications related to cholesteatoma surgery and to determine factors influencing the most common postoperative complication, i.e. SSI in cases with and without mastoid obliteration.

2. Material and methods

2.1. Data acquisition

This is a retrospective review of surgically treated cholesteatomas at the department of Otorhinolaryngology of the Erasmus University Medical Center in Rotterdam, The Netherlands, between 1st of January 2013 and 27th of February 2019. This is a tertiary referral health care center. All operations performed on patients with an age $\geq$18 years were included. All patient charts were reviewed, and the following case characteristics were recorded: gender, patient age at time of surgery, smoking status, side, previous surgery on the operated ear, preoperative ear infection (up to 3 months before surgery), STAMCO stage of the cholesteatoma, intraoperative status of the middle ear mucosa (diseased or not diseased), duration and type of surgery (CWU or CWD, with or without obliteration). Diseased mucosa included all middle ear mucosa conditions except normal mucosa. STAMCO classification is a classification system, based on the extension of the cholesteatoma towards four sites (STAM), complications caused by the cholesteatoma (C) and perioperative state of ossicular chain (O) (Merkus, 2017). The peri- and postoperative management were evaluated, regarding the used reconstruction and obliteration materials and the use of antibiotics. Up to 1 year after surgery all postoperative complications were reviewed. To prevent bias in this retrospective study due to underreporting the presence of transient vertigo, loss of taste, retroauricular hypertrophic scarring and granulation tissue in external ear canal were excluded as a complication. Occurrence of a recurrent or residual cholesteatoma, change in hearing level and/or a whether a dry ear was present after surgery were not included because these factors were considered as goals of the surgery and not as a complication. SSIs of the retroauricular incision were scored by the definition of the Centers for Disease Control and Prevention guidelines (O'Hara, 2018). Early and late SSI were evaluated together. All cases were divided into two groups based on whether a mastoid obliteration was performed or not.

2.2. Surgical technique

All surgeries were performed under general anesthesia by three otologists or (partially) by senior residents under direct supervision. If prescribed, perioperative intravenous antibiotics was admitted prior to incision. A postauricular incision was made, after shaving and skin antisepsis was performed, followed by a mastoidectomy and epitympanotomy. Generally, a CWU technique with obliteration was preferred, however CWD surgery was performed when perioperatively the cholesteatoma turned out to be inaccessible with canal wall up, there was a small mastoid, a complete atelectasis of the middle ear and/or pre-existent (large) defect in posterior canal wall. No obliteration was performed in some cases with an intact ossicular chain and/or in case of uncertainty of complete removal of cholesteatoma.

Cartilage from the cavum conchae and/or fascia temporalis were used for reconstruction of the tympanic membrane. When obliteration was performed, bone chips, bone shavings and bone dust were harvested from the nondiseased cortex. The epitympanum and mastoid was separated from the middle ear by bone chips or cartilage and then obliterated with bone dust and bone shavings. In the case of insufficient autologous obliteration material, bioactive glass granules S53P4 (Bonalive ®, produced by Bonalive Biomaterials Ltd., Turku, Finland) was used as addition to fill the mastoid (without mixing the two filling materials). The obliteration material in the mastoid was in most cases preserved in antibiotics and covered with absorbable hemostatic gelatin sponge (Spongostan ®, produced by Ethicon, Johnson & Johnson Co., USA).

Intracutaneous absorbable sutures or transcutaneous nonabsorbable sutures were used for closure. A ribbon gauze with antibiotic ointment (hydrocortisone/oxytetracycline) was used to pack the ear canal, with or without addition of a silicon sheet. No drain was left. The dressing was removed 1 week postoperatively. Based on surgeon preference, perioperative findings, and status of the middle ear mucosa this was followed by prophylactic ototopical antibiotic eardrops and/or postoperative oral antibiotics for 1 week.

2.3. Statistical analysis

Continuous data were tested for normality using the Shapiro-Wilk test. Normally distributed data were analyzed using independent *t*-test and presented as mean and standard deviation (SD). For non-normal data, the Mann-Whitney *U* test was used and presented using the median and interquartile range (IQR). Chi-square test or Fisher's exact test were performed on categorical data. After univariate analysis, factors with a p value of <0.05 were selected for multivariable analysis and entered in a logistic regression model. To prevent overfitting a maximum of two independent variables was used. A *p*-value of <0.05 was chosen as a threshold of significance. We used IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY) for statistical analyses.

3. Results

3.1. Case characteristics of groups with and without obliteration

Between 2013 and 2019, 336 cholesteatoma operations (so-called cases) were performed on 292 unique patients in our hospital. Case characteristics are summarized in Table 1. Mastoid obliteration was performed in 248 cases and in 88 cases no obliteration was performed. The age at the time of surgery, gender, side, any previous surgery, preoperative infection, technique of surgery and perioperative middle ear mucosal status were not significantly different between the two groups.

However, baseline characteristics were not comparable between the two groups, because the obliteration group consisted of more smokers ($p = 0.008$) compared to the no-obliteration group. Moreover, in the no-obliteration group more STAMCO class 1 and in the obliteration group more STAMCO class 3 cases were present ($p = 0.002$). The duration of surgery in the obliteration group was longer ($p = 0.000$). Furthermore, in the obliteration group more prophylactic perioperative and postoperative antibiotics, as well as prophylactic antibiotic eardrops were prescribed ($p = 0.000$, $p = 0.000$ and $p = 0.004$ respectively). No significant difference in occurrence of postoperative complications ($p = 0.798$) and the number of SSIs (p = 0.520) was observed between the two groups.

Table 1
Case characteristics (n = 336).

		Total n = 336	*No obliteration n = 88 (26%)*	*Obliteration n = 248 (74%)*	p-value
Age at time of surgery in years (median ± IQR)		38 ± 28	36 ± 25	39 ± 28	0.069**
Duration of surgery in hours (mean ± SD)		4:40 ± 1:36	3:20 ± 1:20	5:08 ± 1:24	**0.000**
	Missing data	4 (1%)	-	-	
Gender	Male	221 (66%)	63 (28.5%)	158 (71.5%)	0.181
	Female	115 (34%)	25 (21.7%)	90 (78.3%)	
Side	Left	180 (54%)	53 (29.4%)	127 (70.6%)	0.145
	Right	156 (46%)	35 (22.4%)	121 (77.6%)	
Tobacco use	Yes	115 (34%)	20 (17.4%)	95 (82.6%)	**0.008**
	No	221 (66%)	68 (30.8%)	153 (69.2%)	
Previous surgery	Primary	117 (35%)	25 (21.4%)	92 (78.6%)	0.142
	Secondary	219 (65%)	63 (28.8%)	156 (71.2%)	
STAMCO	Class 1	101 (30%)	39 (38.6%)	62 (61.4%)	**0.002**
	Class 2	108 (32%)	26 (24.1%)	82 (75.9%)	
	Class 3	126 (38%)	23 (18.3%)	103 (81.7%)	
Preoperative infection	Yes	19 (6%)	7 (36.8%)	12 (63.2%)	0.277
	No	317 (94%)	81 (25.5%)	236 (74.5%)	
Type of operation	Canal wall up	282 (84%)	75 (26.6%)	207 (73.4%)	0.699
	Canal wall down	54 (16%)	13 (24.1%)	41 (75.9%)	
Perioperative prophylactic antibiotics	Yes	190 (57%)	16 (8.4%)	174 (91.6%)	**0.000**
	No	146 (43%)	72 (49.3%)	74 (50.7%)	
Perioperative middle ear mucosal status	Diseased	152 (45%)	41 (27.0%)	111 (73.0%)	0.346
	Normal	114 (34%)	25 (21.9%)	89 (78.1%)	
	Missing data	70 (21%)	-	-	
Postoperative antibiotics	Yes	156 (46%)	9 (5.8%)	147 (94.2%)	**0.000**
	No	180 (54%)	79 (43.9%)	101 (56.1%)	
Prophylactic antibiotic eardrops	Yes	249 (74%)	55 (22.1%)	194 (77.9%)	**0.004**
	No	87 (26%)	33 (37.9%)	54 (62.1%)	
Any complication *	Yes	21 (6%)	6 (28.6%)	15 (71.4%)	0.798
	No	315 (94%)	82 (26.0%)	233 (74.0%)	
Postoperative surgical site infection (SSI)	Yes	15 (4%)	5 (33.3%)	10 (66.7%)	0.520
	No	321 (96%)	83 (25.9%)	238 (74.1%)	

* Including SSI, facial nerve palsy, postoperative excessive and prolonged pain
** Mann-Withney U test

3.2. Postoperative complications

In the total group of cases, 21 complications (6.25%) occurred. These included 15 SSIs (4.5%), 4 late onset (temporary) facial nerve palsies (1.2%) and 2 cases with excessive and prolonged pain in the operated area (0.6%). No postoperative deafness was noticed. In the obliteration group no cases with rejection of the obliteration material were observed.

The facial nerve palsies varied between House-Brackmann score 2 (slight) and 4 (moderately severe) and occurred between 5 and 30 days after surgery and were treated with prednisone in 3 cases. In 3 of the 4 cases the facial nerve was fully bony covered perioperatively. In 109 of the 336 cases (32%) the facial nerve was dehiscent during surgery, in 106 cases (32%) this was not described and in 121 cases (36%) the nerve was bony covered. A dehiscent facial nerve was not associated with an increased risk for facial nerve palsy ($p = 0.217$). In all 4 cases facial nerve function fully recovered within 4 weeks.

Two cases had excessive and prolonged postoperative pain in the operated area for which analgetic medication was prescribed. However, due to the lack of structural questioning about postoperative pain, this might be underreported. In neither cases evidence of infection was present. The number of the non-SSI complications was considered too small for further statistical analysis.

3.3. Postoperative surgical site infections

All 15 patients with an SSI presented between 4 days and 55 days after surgery, with a median of 8 days (IQR = 15 days) (see supplementary information, Table S1). Most cases presented with a painful fluctuating, reddish swelling retroauricular, where purulent secretion drained after incision. In 11 cases a culture was done, of which 3 did not show any growth. Four cultures showed a *Staphylococcus aureus*, furthermore single cases of *Pseudomonas aeruginosa, Klebsiella,* Candida and *Propionibacterium acnes* were seen. In 13 cases the infection was successfully treated with an oral antibiotic. In two cases a switch from oral to intravenous antibiotics was needed to control the infection. One case with SSI treated with oral antibiotics required revision surgery after 6 months, because of an ear canal fistula. It took between 2 and 63 days to control to the infection, with a median of 14 days (IQR = 21 days).

3.4. Factors influencing postoperative surgical site infections

Regarding the use of prophylactic antibiotics, in 88 of the 336 cases (26%) no antibiotics were prescribed (neither perioperatively nor postoperatively). Five (5.7%) of them developed an SSI. In 248 of the 336 cases (74%) any form (preoperatively, postoperatively, or both) of prophylactic antibiotics was prescribed. Ten (4.0%) of them developed an SSI. Remarkably, the percentage of SSI occurrence was lowest when only postoperative antibiotics were prescribed (3.4%, 2 SSIs in 58 patients). However, analysis of the four subgroups (no antibiotics, only preoperatively, only postoperatively and both) showed that there were no significant differences ($p = 0.924$) in the development of an SSI. Besides intravenous perioperative antibiotics and oral postoperative antibiotics, antibiotics were also prescribed as postoperative prophylactic eardrops. Subgroup analysis showed no significant differences; however, the number of each subgroup became very small.

All SSIs occurred in cases where the CWU technique was used. In 19 of the 336 cases (5.7%) there was an ear infection preoperatively (up to 3 months before surgery). In 11 of these 19 cases a culture was done, of which two showed a *Staphylococcus aureus,* two

showed a *Pseudomonas aeruginosa,* and single cases of *Haemophilus Influenza* and *Escherichia Coli* were found. The other cultures were negative. None of them developed an SSI. In 9 of the 336 cases (2.7%) a retroauricular fistula was present before surgery, of which 1 case developed an SSI (10% versus 4.3%, $p = 0.371$).

Because the no-obliteration group and the obliteration group were not comparable in baseline characteristics, they were analyzed separately regarding the occurred SSIs. In both groups gender, side, tobacco use, STAMCO classification, preoperative infection, duration of surgery, technique of surgery and perioperative middle ear mucosal status were not significantly different between the SSI and the no SSI cases.

In the 88 cases where no mastoid obliteration was performed, 5 SSIs occurred (5.7%). In the univariate analysis of this group, the following factors were significantly correlated with SSI: a lower age at time of surgery and primary surgery, shown in Table 2. Due to the low number of SSI in this no-obliteration group no multivariate analysis could be performed.

In 248 cases mastoid obliteration was performed, of which 10 cases (4.0%) developed an SSI. The first mastoid obliteration in our clinic was performed in 2013. Although no difference in occurrence of SSI was found whether an antibiotic solution was used to preserve the obliteration material in or not (p = 0.692), a trend was noticed after a protocol change. Since 26th March 2015 the obliteration material was preserved in rifampicin instead of cefazolin solution. The SSI occurrence rate decreased from 8.1% (6 of 74 cases) to 2.3% (4 of 174 cases) ($p = 0.069$) after this change. The choice for rifampicin, cefazolin, or amoxicillin/clavulanic acid to preserve the obliteration material in did not significantly change the risk on SSI ($p = 0.064$).

In the univariate analysis of the obliteration group, the only factor that was significantly correlated with SSI was the use of BAG S53P4 ($p = 0.005$), see Table 3. In 49 of the 248 cases (20%) BAG S53P4 was used as addition to fill the mastoid. In 6 of these 49 cases (12%) an SSI occurred. Multivariable logistic regression model analysis showed that the use of BAG S53P4 was independently associated with the development of SSI ($p = 0.008$, OR 5.940, 95% CI 1.578–22.361).

4. Discussion

This study reported on the occurrence of postoperative complications related to cholesteatoma surgery, to determine factors influencing the most common complication, i.e. SSI in cases with and without mastoid obliteration. Based on National Nosocomial Infection Surveillance (NNIS) system reports, SSIs account for 38% of all nosocomial infections (Mangram, 1999). Reported incidences of an SSI in ear surgery vary around 10% (ranging between 3.9% – 25%) (Bastier, 2016; Black, 1998; Gantz, 2005; Walker, 2014). Several studies evaluated the role of prophylactic antibiotics to prevent these SSIs in ear surgery, with different outcomes (Gantz, 2005; Govaerts, 1998; Patel, 2018; Pierce, 2016). A Cochrane review showed no significant evidence that antibiotic prophylaxis was helpful in reducing SSIs in clean and clean-contaminated ear surgery (Verschuur, 2004). This is in line with our findings that the use of perioperative and postoperative prophylactic antibiotics did not change the risk for an SSI (regardless of the obliteration status). However, whether cholesteatoma surgery is a clean-contaminated, contaminated, or dirty surgical field is subject of discussion and possibly not all cholesteatoma surgery can be attributed to the same class (Mangram, 1999). If so, patient selection might explain the contradictory results of others who reported up to a 10-fold decreased infection rate after given perioperative antibiotic prophylaxis (Gantz, 2005; Pierce, 2016). Another explanation for the conflicting results in literature is that not all studies were executed according to the general principles of prophylaxis. The principles of SSI prevention state that antibiotic prophylaxis should be optimally administer 4 min before incision, should target the most likely pathogens *(Staphylococcus Aureus and Pseudomonas species*), and should be discontinued within 24 h (Govaerts, 1998; Koch, 2013; Mangram, 1999; Mustafa, 2008).

The fact that in our study more perioperative and postoperative antibiotics were prescribed in the obliteration group may be provoked by the knowledge that the duration of an obliteration is longer and foreign body filling material might be used. These factors are known to influence the risk of SSI development (Mangram, 1999). Nonetheless, our results show that obliteration itself did not give a higher risk on SSI (5.7% risk if not obliterated versus 4.0% if obliterated). However, the low number of occurred SSI's might be underpowered to rule out any significant difference.

The STAMCO class 3 was more represented in the obliteration group ($p = 0.002$), which means that the cholesteatomas in this group were more extensive that in the no-obliteration group. This can be due to a selection bias where the surgeon performs an obliteration more easily in case of a more extensive cholesteatoma. The obliteration group also contained more smokers ($p = 0.008$), which might be another explanation of more extensive cholesteatomas in this group. In literature it has been suggested that tobacco smokers have more aggressive and extensive cholesteatomas compared to nonsmokers (Kaylie, 2009). Nicotine directly and indirectly leads to vasoconstriction, which reduces tissue perfusion necessary for wound healing, and increases the risk to develop an SSI (Golub, 2015; Kay-Rivest, 2019). We could not confirm this in our study. This might be attributed to the fact that we did only assess whether our patients smoked at the time of surgery and did not inquire about history of smoking. Kaylie et al. found that former smokers who quit less than 5 years have similar outcomes to smokers, whereas those who quit for more than 5 years were

Table 2
Risk of SSI in the cases without obliteration (n = 88).

		Total n = 88	*Surgical site infection (SSI) n = 5*	p-value
Age at time of surgery in years (median ± IQR)		36 ± 25	21 ± 8	**0.006***
Previous surgery	Primary	25 (28%)	4 (16.0%)	**0.022**
	Secondary	63 (72%)	1 (1.6%)	
Preoperative infection	Yes	7 (8%)	0 (0.0%)	1.000
	No	81 (92%)	5 (6.2%)	
Perioperative prophylactic antibiotics	Yes	16 (18%)	0 (0.0%)	0.580
	No	72 (82%)	5 (6.9%)	
Postoperative antibiotics	Yes	9 (11%)	0 (0.0%)	1.000
	No	79 (89%)	5 (6.3%)	
Prophylactic antibiotic eardrops	Yes	55 (63%)	4 (7.3%)	0.646
	No	33 (37%)	1 (3.0%)	

* Mann-Withney U test

Table 3
Risk of SSI in the cases with obliteration (n = 248).

		Total n = 248	*Surgical site infection (SSI) n = 10*	p-value
Age at time of surgery in years (median ± IQR)		39 ± 28	36 ± 33	0.810*
Previous surgery	Primary	92 (37%)	3 (3.3%)	0.749
	Secondary	156 (63%)	7 (4.5%)	
Perioperative prophylactic antibiotics	Yes	174 (70%)	8 (4.6%)	0.728
	No	74 (30%)	2 (2.7%)	
Antibiotics used for filling material	Yes	198 (80%)	9 (4.5%)	0.692
	No	50 (20%)	1 (2.0%)	
Which antibiotics used for filling material	Rifampicin	135 (68%)	3 (2.2%)	0.064
	Cefazolin	62 (31%)	6 (9.7%)	
	Amoxicillin/ clavulanic acid	1 (1%)	0 (0.0%)	
Bioactive glass (BAG) S53P4 use	Yes	49 (20%)	6 (12.2%)	**0.005**
	No	199 (80%)	4 (2.0%)	
Absorbable hemostatic gelatin sponge cover	Yes	98 (40%)	7 (7.1%)	0.054
	No	150 (60%)	3 (2.0%)	
Postoperative antibiotics	Yes	147 (59%)	7 (4.8%)	0.744
	No	101 (41%)	3 (3.0%)	
Prophylactic antibiotic eardrops	Yes	194 (78%)	10 (5.2%)	0.124
	No	54 (22%)	0 (0.0%)	

* Mann-Withney U test

similar to never-smokers (Kaylie, 2009).

Remarkable was our finding that the additional use of BAG S53P4 had a higher risk on SSI in the obliteration group, compared to the use of autologous bone dust and bone shavings alone (p = 0.008, OR 5.940, 95% CI 1.578–22.361). BAG S53P4 is named after its chemical composition of 53% SiO2 and 4% P2O5. BAG S53P4 has a growth-inhibitory effect on the most common aerobic and anaerobic ear pathogens, including *Staphylococcus aureus, Pseudomonas aeruginosa, Propionibacterium anes* and Candida, which are clinically relevant in ear surgery (Lepparanta, 2008; Munukka, 2008). This effect is presumably based on an induced elevation of the pH and osmotic effects caused by the nonphysiological concentration of ions dissolved by the glass.

Several studies reported on SSI after mastoid obliteration with BAG S53P4 in the management of chronic otitis media with and without cholesteatoma (Bernardeschi, 2015; de Veij Mestdagh, 2017; Król, 2021; Leonard, 2021; Mishra, 2021; Sarin, 2012; Schimanski, 2015; Silvola, 2012; Sorour, 2018; Stoor, 2010; Vos, 2017) (see supplementary information, Table S2). The SSI rates in these studies vary from 0 to 2% and are lower compared to our rate of 12%, except for Silvola et al. who reported 38% infection rate. However, in this latter study it was not specified whether the infections concerned retroauricular SSI or persistent otorrhea.

Postoperative use of a drain was not included in our protocol. Schimanski et al. concluded that in the case of obliteration with BAG S53P4 postoperative use of a drain was beneficial to avoid accumulation of seroma fluid in the mastoid and thereby reducing the risk on an SSI (Schimanski, 2015). Also, in other studies where a drain was used postoperatively no SSIs were reported (Veij Mestdagh, 2017; Vos, 2017).

Another possible explanation for the higher number of SSIs in our study may lay in the used surgical technique: other studies only used BAG S53P4 as obliteration material, whereas we used BAG S53P4 as addition to bone dust and bone shavings. The two filling materials were not mixed. In our group where only bone dust and bone shaving were used to obliterate, an SSI rate of 2.0% was noticed. This suggests that harvesting or preserving the bone dust or bone shavings itself are not the causes of the higher infection rate. Although the number of included operations was large, subgroups (like the one where BAG S53P4 was used) became smaller. Whether the combination of BAG S53P4 and bone dust is the cause of the higher SSI rate cannot be excluded from this study, however this can neither be confirmed.

Furthermore, 3 out of 10 SSIs in the BAG S53P4 obliteration group occurred more than 30 days after surgery. Evaluating early and late SSIs together might negatively affect our results, compared to others. Whether the size of the mastoid influenced the choice to use BAG S53P4 and this size was related to the occurrence of an SSI could not be answered in this study. Further prospective research is needed to answer which of the above and/or other factors be of influence on the higher number of SSIs in the BAG S53P4 obliteration group.

In our study we had an overall SSI incidence of 4.5% (15 of 336 cases). This percentage meets the findings of Gantz et al. who decreased their number of SSIs after a protocol change from 14.3% to 4.5% (Gantz, 2005). After two years of experience with obliteration they started using 48 h perioperative intravenous antibiotics, washing of the harvested cortical bone in antibiotic solution and leaving a drain in the surgical field for 48 h (Gantz, 2005). In our study, we also observed a reduction of SSI after the first two years from 8.1% to 2.3%. We did not find evidence that this reduction can be ascribed to the antibiotics used for the obliteration material, neither to the duration of surgery. Walker et al. suggested that their reduction in infection rate from 10% to 5.6% after the first 90 patients was ascribed to their change in collecting the bone pate only from the cortex (Walker, 2014). Perhaps, stop harvesting before mastoid air cells are visible and keeping the obliteration material aseptic until use, is subject to a learning curve.

The causes of SSI are certainly multifactorial. We cannot exclude that any of the other known operation characteristics that may influence the risk of SSI development had impact on our results. These factors include duration of surgical scrub, skin antisepsis, preoperative shaving, operating room ventilation, inadequate sterilization of instruments and surgical technique (poor hemostasis, failure to obliterate dead space and tissue trauma) (Mangram, 1999).

In total 21 complications (6.25%) were evaluated, including 15 SSIs (4.5%), 4 (temporary) facial nerve palsy (1.2%) and 2 cases with excessive and prolonged pain in the operated area (0.6%). Our occurrence of temporary facial nerve palsy was on the lower limit of earlier reported incidences of 0.5 – 4% after otologic surgery (Heilbronn, 2020). The prognosis of the observed delayed facial nerve palsies was excellent in accordance with literature (Bae, 2019).

4.1. Limitations

The retrospective design of this study caries several inherent problems, such as possible indication bias, analysis of data from heterogeneous groups and non-systematic data collection methods. We do not have full information on the preoperative decisions made, neither on the postoperative presence of complications like postoperative pain, transient vertigo, loss of taste, retroauricular hypertrophic scarring and granulation tissue in external ear canal. For future perspectives a prospective study where these parameters are scored could give additional answers.

5. Conclusions

SSI is the most common postoperative complication in cholesteatoma surgery. No difference was observed in the development of an SSI whether perioperative and/or postoperative prophylactic antibiotics were prescribed or not. The use of BAG S53P4 in combination with bone dust and bone shavings for mastoid obliteration was associated with an increased risk for SSI in our study population. The causes of SSI are multifactorial, therefore further prospective research is needed to answer whether the lack of using a postoperative drain, the combination of BAG S53P4 with bone dust, and/or a learning curve are of influence to explain our contradictory result compared to previous literature.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joto.2021.10.001.

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