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Original Article

Safety and Patients' Satisfaction of Fungal Ball Removal in the Maxillary Sinus under Local Anesthesia

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SUMMARY

Background: The treatment of choice for maxillary fungal ball (FB) is surgical removal; however, surgeons hesitate to perform surgery, especially in elderly individuals, under general anesthesia (G/A). So instead of G/A, this study evaluated the outcome of FB removal under local anesthesia (L/A). Methods: Three analyses were included in this study. First, the demographic characteristics of patients with FB were analyzed via a retrospective chart review of 3,681 individuals who underwent otolaryngologic surgery; FB, chronic sinusitis (CRS), chronic otitis media, deviated septum, and enlarged tonsil. Second, the clinical characteristics of patients who had surgery for FB under L/A were compared to those of patients who had surgery for CRS under L/A via age-sex matched case-control analyses. Third, the clinical characteristics of elderly patients with FB were compared to those of non-elderly patients. Results: Comparisons within the otorhinolaryngological disease group showed that patients with FB were older and had a higher proportion of women than the other groups. Age- and sex-matched case-control analyses with the CRS group revealed that FB patients complained of less pain (p = 0.05) and reported more satisfaction with L/A than the CRS group (p = 0.002). Analyses by age group showed that elderly patients with FB had lower sinonasal outcome test scores but higher Lund-Mackay scores. Conclusion: Old age, diabetes, and hypertension, which may increase the risk for general anesthesia, are characteristic of patients with FB in this study. However, patients who underwent FB removal under L/A had relatively less pain, greater satisfaction than CRS with L/A. Thus, surgical removal under L/A is a safe, reasonable option for patients with FB.

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1. Introduction

Aging is a physiological phenomenon that causes structural and functional degeneration. 1-4 Due to diffuse functional deterioration, patients are more sensitive to anesthetic agents and are particularly sensitive to the stresses of hospitalization, surgery, and anesthesia. Although the most significant risk predictor for surgical morbidity is the site of surgery, surgeons do not consider surgery on elderly patients under general anesthesia (G/A) a safe option. In these situations, regional block and surgery under local anesthesia (L/A) may be an excellent substitute for G/A. For example, sphenopalatine block and anterior ethmoid block can be performed to reduce surgical morbidity instead of G/A in the ear, nose, and throat (ENT) field. Fungal balls (FBs) are non-invasive mass-like lesions that usually involve a single sinus, mainly the maxillary sinus or sphenoid sinus. 5,6 Different from the invasive form, the FB has female dominance and is more prevalent in immune-competent patients. The treatment of choice for FBs is complete surgical removal without the use of antifungal agents. However, surgeons hesitate to perform surgery under

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G/A, particularly in elderly patients. 1

In this study, we compared the clinical characteristics of patients with FBs to those of patients with other ENT diseases (e.g., chronic rhinosinusitis [CRS], chronic otitis media [COM], deviated nasal septum, and enlarged tonsils) to determine if patients with FB were really aged. Then, to reduce the confounding effects of age and sex, age-sex adjusted medical conditions, pain, and patient satisfaction with surgery under L/A were compared to those for a similar rhinologic disease, CRS. Lastly, we compared the characteristics and treatment results between elderly and non-elderly patients with FBs.

2. Materials and methods

2.1. Patients

Four disease groups with the greatest number of patients undergoing surgery at our hospital were selected as the control group to identify the demographic characteristics of the FB group. Hence, a retrospective chart review of 3,685 patients including 212 with mycetoma, 730 with CRS, 1624 with COM, 686 with deviated nasal septum, and 433 with enlarged tonsil(s) was performed to analyze the demographic characteristics of patients with a FB. All patients who underwent surgery from July 2010 to June 2016 in a tertiary hospital were included. Demographic factors such as age

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and sex were analyzed. In addition, the clinical characteristics of the FB group were compared to those of a similar rhinologic disease group (CRS group). Considering the difference in age and sex between groups, age- and sex-matched case-control analyses were performed. A total of 100 patients with FB were identified in consecutive order among 212 patients, and were designated the FB group. Each case had one control matched for age (10-year age group) and sex in consecutive order among 730 patients with CRS. Medical conditions, intraoperative pain, and patient satisfaction with L/A were evaluated. Intraoperative pain and patient satisfaction with L/A were assessed by 10 cm visual analogue scale (VAS) scores. 8,9 Regarding pain, a score of 10 indicated the worst pain conceivable, and a score of 0 indicated no pain. Regarding patient satisfaction, a score of 5 indicated a neutral preference for both types of anesthesia. A score of 10 indicated full satisfaction with L/A and wanting L/A in their next similar surgical procedures, and a score of 0 indicated worst satisfaction with L/A and wanting G/A in their next similar operations. Finally, the elderly and non-elderly FB groups were compared to analyze the clinical characteristics of the elderly population. Patients aged 65 or older were designated elderly according to Medicare standards. Patients aged less than 65 were designated non-elderly. Demographic factors, preoperative Lund-Mackay (LM) score, 10 scores of sinonasal outcome test (SNOT), 11,12 surgical morbidity, and recurrence rate were analyzed. The Institutional Review Board of a tertiary hospital approved this study protocol (CNUH-2017-198).

2.2. Surgical technique for fungal ball removal under local anesthesia

All the patients in the Table 2 underwent surgery under L/A for their FB or CRS. A mixture of 4% lidocaine 60 mL and epinephrine (1 mg/mL) 20 mL on a soaked cotton pledget was inserted through the middle meatus. Sphenopalatine and anterior ethmoid block were performed with lidocaine epinephrine injection (1:100000, 1 mL), each with a 23G needle. To provide a transnasal corridor to the fungal material, an endoscopic middle meatal antrostomy (MMA) was made following the conventional endoscopic sinus surgery technique. 13 A uncinectomy was performed using a sickle knife or cottle elevator. The natural ostium of the maxillary sinus was identified, and ostial enlargement was performed as large as possible. The natural ostium of the maxillary sinus was identified and fungal material was identified using 30° and 70° endoscopy. The ostium was enlarged according to the situation. After adequate antrostomy had been made, fungal material was removed via MMA using ball-tip curved suction or 90-degree giraffe forceps.

2.3. Statistical analyses

The chi-square test was used to compare categorical variables

between the FB group and CRS group. The independent samples t-test was used to compare continuous variables such as age, follow-up duration, SNOT-25, LM scores, and VAS scores. All statistical analyses were performed using IBM SPSS Statistics for Windows v. 20.0 (IBM Corp, Armonk, NY, USA). Two-sided p values < 0.05 were considered statistically significant.

3. Results

A total of 212 patients with mycetoma, 730 with CRS, 1,624 with chronic otitis media, 686 with deviated nasal septum, and 433 with enlarged tonsil(s) were enrolled in this study. Demographic characteristics of the mycetoma group were significantly different from those of the other otolaryngological surgery groups (Table 1). The mean age of the FB group was 64.06 years and was significantly greater than that of the other groups (p < 0.001). The proportion of elderly individuals in the FB cohort was 51.4%. In addition, female predominance was noted in the FB group. Considering the old age and female predominance of the FB group, age- and sex-matched analyses of 100 patients with CRS group and 100 patients with FB group were performed to control for confounding effects of age and sex (Table 2). The presence of hypertension (HTN) was significantly higher (p=0.043, Table 2). However, the LM score was significantly higher in the CRS group as expected. The SNOT score was significantly lower in the FB group. In addition, the FB group showed less pain (p = 0.05) and higher satisfaction with L/A (p = 0.002, Fig. 1). The VAS satisfaction scores of the CRS group and fungal group were 5.54 \pm 3.66 and 8.42 \pm 2.59, respectively. The clinical characteristics of the elderly FB population and non-elderly FB population were compared (Table 3). A total of 103 patients were grouped as elderly and 109 patients were non-elderly. Mean age was significantly different

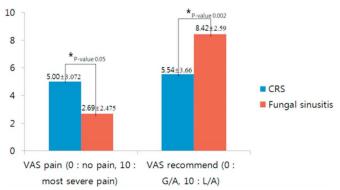


Fig. 1. Age distribution according to disease. CRS denotes chronic rhinosinusitis; VAS, visual analogue scale; VAS pain, subjective pain of patients during surgery; VAS recommend, preference to the types of surgery. A score 5 indicate neutral preference to both types of anesthesia. A score of 10 indicated the fully satisfied with their local anesthesia (L/A) and want a surgery under L/A in next similar surgical procedures, and a score 0 indicated worst satisfaction to their L/A and want G/A in their next similar operations.

Table 1Demographic characteristic of the patients with fungal ball and other otolaryngologic disease*.

Characteristic	Total	Fungal sinusitis	CRS	COM	Deviated nasal septum	Enlarged tonsils	p-value*
Patients, n	3685	212	730	1624	686	433	
Age,	45.26 ± 19.65	64.06 ± 10.57	47.37 ± 17.81	51.11 ± 14.92	40.90 ± 17.03	17.00 ± 16.86	< 0.001
Children (< 18 years)	884	0 (0)	58 (7.95)	74 (4.56)	44 (6.41)	267 (61.66)	< 0.001
Adults (< 64 years)	1780	103 (48.6)	550 (75.34)	1281 (78.88)	585 (81.70)	157 (35.26)	< 0.001
Elderly (≥ 65 years)	1017	109 (51.4)	122 (16.71)	269 (16.56)	57 (8.31)	9 (2.08)	< 0.001
Female sex	1626	137 (64.6)	265 (36.3)	953 (58.7)	111 (16.2)	160 (37.0)	< 0.001

Data are presented as n (%) unless otherwise indicated. * The student t-test was used to analyze age. The x2 and Fisher's exact test were used to analyze the sex, age distribution. CRS denotes chronic rhinosinusitis; COM denotes chrocnic otitis media.

Table 2
Clinical characteristics of patients with chronic sinusitis (CRS) and fungal ball. An age- and sex-matched comparison*.

	CRS	Fungal ball	p value/OR/95% CI
Number of patients	100	100	
Age	63.77 ± 10.45	63.72 ± 9.76	0.972/controlled
Gender (M/F)	35/65	35/65	1.000/controlled
HTN	33	48	0.043/1.874/1.057-3.322
DM	16	27	0.084/1.942/0.971-3.884
LM score	6.36 ± 2.53	$\textbf{4.33} \pm \textbf{2.47}$	< 0.001
SNOT-25	37.93 ± 24.70	27.65 ± 22.43	0.032

^{*} The x2 and Fisher's exact test were used to analyze the sex, age. HTN denotes hypertension; DM, diabetes mellitus; LM score, Lund-Mackay score.

Table 3
Clinical characteristics of 212 patients with fungal ball according to age groups*.

	Total	Adult (< 65)	Elderly (≥ 65)	p value
Number	212	103	109	
Age	64.06 ± 10.57	55.41 ± 7.51	$\textbf{72.40} \pm \textbf{5.41}$	< 0.001
Gender				
Female	137	70 (68.0%)	67 (61.5%)	0.325
Underlying ds				
DM	55	26 (25.2%)	29 (26.6%)	0.876
HTN	103	41 (13.6%)	62 (26.9%)	0.014
F/U duration				
Months		$\textbf{9.39} \pm \textbf{11.6}$	$\textbf{7.39} \pm \textbf{10.0}$	0.180
Revision surgery	12	9 (8.73%)	3 (2.75%)	0.076
LM score	$\textbf{4.30} \pm \textbf{2.21}$	$\textbf{3.93} \pm \textbf{1.97}$	4.73 ± 2.55	0.010
SNOT-25				
Pre-op	27.65 ± 22.43	$\textbf{37.88} \pm \textbf{24.84}$	$\textbf{18.89} \pm \textbf{15.87}$	0.002
Post-op	$\textbf{13.0} \pm \textbf{17.2}$	17.90 ± 22.79	8.00 ± 8.13	0.084
VAS score				
VAS pain	2.69 ± 2.475	$\textbf{3.3} \pm \textbf{2.41}$	2.25 ± 2.33	0.140
VAS recommend	8.42 ± 2.59	$\textbf{8.30} \pm \textbf{2.65}$	8.50 ± 2.44	0.510

^{*} The student t-tests were used to analyze the age, revision surgery, F/U duration, LM score and SNOT-25 score. The x2 and Fisher's exact test were used to analyze the sex, age, underlying ds and .DS site denotes disease site; F/U duration, follow up duration; SNOT, sinonasal outcome test.

according to group as expected. However, sex, site of disease, follow-up duration, revision rate, and prevalence of diabetes mellitus (DM) showed no difference. Prevalence of HTN was significantly higher in the elderly group (Table 3, p = 0.014). The prevalence of HTN in the non-elderly and elderly populations within the FB group was 13.6% and 26.9%, respectively. In addition, elderly patients showed significantly higher LM scores (p = 0.010) but lower SNOT scores (p = 0.002, Table 3). Although the elderly population showed a lower SNOT score and higher LM score, their satisfaction with surgery was not difference from that of the non-elderly. In addition, no patient failed to undergo surgery or had surgical morbidity in the FB group.

4. Discussion

Demographic factors of the FB group were different from those of another patient group. The mean age of the FB group was significantly higher than that of patients with CRS (Table 1). Age distribution also differed from that of other patient groups. However, the proportion of the elderly population in the FB group was more than 50%. In addition, the FB group in this study showed female predominance in accordance with previous studies. On the other hand, the CRS group showed male predominance. ¹⁴ These results are in accordance with a previous study by Ferreiro et al., ¹⁵ in which the authors also concluded that FB occurs in an elderly population and has female predominance.

According to world population prospects in 2015 from the UNDESA Population Division, the population of elderly people is gradually growing, and is anticipated to account for 16.5% and 21.5% of the total population in 2030 and 2050, respectively. ¹⁶ The number of patients with FB is also expected to increase in the future. ¹⁴ In addition, aging is a physiological phenomenon that causes structural and functional degeneration. ¹ It affects all organ systems such as the cardiovascular, respiratory, renal, and nervous systems. ¹ Due to diffuse functional deterioration, patients are more sensitive to anesthetic agents and particularly sensitive to the stresses of hospitalization, surgery, and anesthesia. Ban et al. ¹⁷ reported that the overall complication rate of Endoscopic Sinus Surgery (ESS) in an elderly population was more than 30%, whereas that of a non-elderly population was only 11%.

FB in the maxillary sinus requires surgery to remove fungal material and facilitate aeration of the involved sinuses. With the advent of endoscopic technique, endoscopy approaches have replaced external approaches in many surgical fields. ^{18,19} Before the advent of endoscopic surgical technique for sinus disease, the Caldwell-Luc procedure was the mainstay for fungal removal. However, after the advent of the ESS technique, endoscopic approaches for FB have become more popular than the Caldwell-Luc operation²⁰ which is not often performed under L/A. On the other hand, ESS can be performed under either G/A or L/A. However, the clinical characteristics of patients with FB are not favorable for surgery under G/A, as they tend to be relatively old with many medical comorbidities such as DM and HTN.

ESS is a common procedure for sinusitis that can be performed under either L/A or G/A. G/A allows an immobile surgical field, effective airway protection, adequate analgesia, and patient comfort, ^{21,22} and is preferred for most CRS cases to meet challenging surgical needs. However, FB usually involves only one sinus. ²² In this study, the LM score was significantly lower in the FB group than in the CRS group (Table 2). In most cases, MMA, which can be conducted within 30 min, was enough for FB removal. Hence, the operation time, blood loss, and requirement for analgesic agent might be less in the FB group. On the other hand, the FB group was significantly older than the CRS group (Table 1), and showed significantly higher medical comorbidity (Table 2). So if patients can endure the discomfort of L/A, and if they want surgery under L/A, FB removal under L/A can be a good alternative to surgery under G/A.

Subjective pain score and patient satisfaction score with surgery also support surgery under L/A in the FB group. We compared the intraoperative pain of the FB group to that of the CRS group. Pain assessed by VAS score was significantly lowerin the FB group. This is a reasonable result because disease severity, which was assessed by LM score, was lower in the FB group. In addition, we evaluated patient satisfaction with their preference for types of anesthesia. We asked the patients whether they might want the same surgery under G/A or L/A, if they should undergo a similar procedure. Patients with

FB who had surgery under L/A showed a significantly higher preference for L/A. On the other hand, patients with CRS who had surgery under L/A showed a neutral preference (Fig. 1).

The clinical characteristics of patients with FB according to age groups (Table 3) were analyzed. No previous reports have analyzed the clinical characteristics of FB according to age groups. Preoperative SNOT score was significantly lower but the LM score was higher in the elderly group. The prevalence of asymptomatic incidental detection of FB during brain imaging and characteristics of pain tolerance in elderly people might be explanations for the low SNOT score. ^{23,24}

This study was a retrospective, non-randomized, non-placebo-controlled study, which might have led to statistical bias. Thus, the study analyzed three statistical populations. First, a population with representative otolaryngologic diseases was analyzed to validate the genuine demographic characteristics of the FB group (Table 1). Second, age- and sex-matched comparisons of FB and CRS groups were performed to adjust for the confounding effects of age and sex on medical conditions, pain, and preferences for types of surgery (Table 2 and Fig. 1). Third, the clinical characteristics of FB according to age groups were analyzed within the FB population (Table 3).

The technique for G/A or painless anesthesia for operation has improved greatly. Patients can undergo surgery without pain under G/A, and surgeons may prefer surgery under G/A. However, many patients wrongly believe that G/A affects memory or other brain functions. In addition, they think they cannot be aware of ghost surgery under G/A. In these situations, surgery under L/A can be a good alternative for patients with a FB.

5. Conclusion

Old age, female sex, DM, and HTN were clinical characteristics of FB in this study, some of which were considered high risk for G/A. In addition, patients who underwent FB removal under L/A showed less pain with more satisfaction than a CRS group without serious adverse events. Thus, FB removal under L/A may be a reasonable and safe option for elderly patients.

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Declaration of any potential financial and non-financial conflicts of interest

No financial relationships relevant to this article to disclose. The authors have no conflicts of interest to disclose.

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