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Otology

Quality of life after cholesteatoma surgery: comparison between surgical techniques

Qualità di vita dopo chirurgia del colesteatoma: confronto fra tecniche chirurgiche

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SUMMARY

Objective. To evaluate the long-term quality of life (QoL) in patients operated for cholesteatoma by canal wall-up tympanoplasty (CWUT) or canal wall-down tympanoplasty (CWDT) with mastoid obliteration.

Methods. QoL was evaluated by the Chronic Otitis Media Questionnaire - 12 (COMQ-12). For each patient, the total score and three partial subscores, concerning disease activity, functional impairment and general impact on the patient's life were calculated. These scores were correlated with the surgical technique, as well as anatomical and functional results.

Results. 68 procedures were classified as CWUT and 78 as CWDT with obliteration. The mean follow-up was 65 months. Total and partial COMQ-12 scores did not show any significant difference between the two groups. Correlation analysis showed a significant direct association between the postoperative Air-Bone Gap (ABG) and both the COMQ-12 total score and functional subscore in the CWUT group.

Conclusions. This is the first study comparing CWUT and CWDT with obliteration with the COMQ-12, thus confirming the overlapping results in terms of QoL. These findings, together with the evidence of the significantly lower rates of recidivism, show that CWDT with obliteration should be considered as a good alternative to CWUT.

KEY WORDS: cholesteatoma, canal wall-down, obliteration, quality of life, COMQ-12

RIASSUNTO

***Obiettivo**. Valutare la qualità di vita (QoL) a lungo termine nei pazienti sottoposti a timpanoplastica chiusa (CWU) o aperta (CWD) obliterativa per colesteatoma.*

***Metodi**. La valutazione della QoL è stata eseguita tramite il Chronic Otitis Media Questionnaire-12 (COMQ-12). Per ciascun caso sono stati calcolati un punteggio totale e tre parziali, riferiti all'attività di malattia, all'aspetto funzionale e all'impatto sulla vita. Questi sono stati poi correlati alla tecnica chirurgica e ai risultati anatomici e funzionali.*

***Risultati**. 68 procedure sono state classificate come CWU e 78 come CWD obliterativa. Il follow-up medio è stato di 65 mesi. I punteggi parziali e totali di COMQ-12 non hanno mostrato alcuna differenza significativa tra i due gruppi. L'analisi di correlazione ha mostrato, nel gruppo CWU, un'associazione diretta tra l'Air-Bone Gap (ABG) postoperatorio ed entrambi i punteggi di COMQ-12 totale e funzionale.*

***Conclusioni**. Questo è il primo studio che ha confrontato tecniche chiuse e aperte obliterative attraverso l'uso del COMQ-12, confermando risultati sovrapponibili in termini di QoL. Questa evidenza, unita a quella del più basso rischio di recidiva, mostra come la timpanoplastica aperta obliterativa debba essere considerata una valida alternativa alla timpanoplastica chiusa.*

PAROLE CHIAVE: *colesteatoma, timpanoplastica aperta, obliterativa, qualità di vita, COMQ-12*

Introduction

The surgical management of cholesteatoma remains one of the most debated topics in otology. Surgery has been traditionally classified into canal wall-up

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tympanoplasty (CWUT) and canal wall-down tympanoplasty (CWDT), depending on the preservation or removal of the posterior bony wall of the external auditory canal (EAC). While the preservation of the posterior EAC wall maintains an anatomically "normal" middle ear and mastoid cleft, its removal allows better exposure of the middle ear and reduces the risk of residual and recurrent disease [1]. CWDT has, however, been associated with frequent side effects such as debris accumulation, frequent ear discharge, vertigo and difficulty in hearing aid fitting [1,2].

In the recent literature, the quality of life (QoL) of patients operated on for cholesteatoma has become a increasing topic of interest. Besides the classical outcome measures, such as recurrence rate and hearing function, different questionnaires evaluating the QoL of patients affected by chronic otitis media have been proposed [3-6]. The Chronic Otitis Media Questionnaire - 12 (COMQ-12) has been recently developed by Phillips [7] and validated in several languages, including Italian [8].

The results of CWUT and CWDT have been reported by several authors in terms of auditory outcomes, complications and recurrence rates; however, only few studies have considered postoperative QoL [9,10].

The aim of the present study was to compare CWUT with CWDT with mastoid obliteration in terms of long-term postoperative QoL using the COMQ-12 questionnaire [7] and to correlate this score with the traditional outcome measures.

Materials and methods

Two-hundred eighty-two consecutive surgical procedures performed for middle ear and mastoid cholesteatoma at our Department between January 2009 and December 2014 were retrospectively evaluated. Such a period was chosen with the purpose of having at least 5-years of follow-up for all patients. Patients undergoing revision or second-look surgery or affected by congenital and petrous bone cholesteatoma were excluded.

All surgeries were performed by the senior author as an inpatient service with a retroauricolar or transcanal microscopic approach. All patients underwent preoperative tonal audiometry and high-resolution computed tomography (HRCT). The selection of the proper technique was made pre- and intra-operatively in consideration of the extension of disease, anatomical conformation and presence of complications. In particular, a transcanal approach was performed in cases of cholesteatoma located in the middle ear space and limited to the posterior mesotympanum. CWDT was preferred in case of larger cholesteatomas or in the presence of complications such as large labyrinthine or cochlear fistula, large erosion of the posterior canal wall, or facial nerve palsy [11]. CWUT was performed in 128 cases (45.4%), while CWDT with obliteration was carried out in 154 cases (54.6%). Twenty-nine patients underwent a transcanal tympanoplasty and were considered in the CWUT group. Obliteration of the mastoid cavity was always performed in CWDT by autologous bone paté [9]. In 69.2% of cases (81.3% of CWUTs and 57.1% of CWDTs) surgery was staged, with the second stage performed at 12-18 months from the first surgery with the aim of early detection of residual cholesteatoma and reconstruction of the ossicular chain. Histology confirmed cholesteatoma in all cases.

All patients were submitted to clinical follow-up, while unstaged CWUT patients or those who refused the second-look procedure underwent HRCT 18-24 months after primary surgery.

All patients were evaluated by preoperative and serial postoperative micro-otoscopy and pure-tone audiometry. These data, together with surgical and follow-up reports, were collected from medical records and integrated in an electronic database. Pure-tone average (PTA) values were calculated as the mean of 0.5, 1, 2 and 4 kHz thresholds, Air-Bone Gap (ABG) as the difference between air conduction PTA (PTA_{AC}) and bone conduction PTA (PTA_{BC}). Finally, Delta-BC was calculated as the difference between the postoperative and preoperative average thresholds at 1, 2 and 4 kHz, as the possible expression of a sensorineural damage. Functional results were expressed in terms of postoperative ABG and ABG improvement, calculated as the difference between preoperative and postoperative ABGs. All data are presented in accordance with recommendations from the Hearing Committee of the American Academy of Otolaryngology – Head and Neck Surgery for the evaluation of conductive hearing loss [12].

From these 282 interventions, we selected cases suitable for COMQ-12 administration, thus excluding patients younger than 16 years or older than 85 years at the time of the investigation. Since the study was conducted in July 2020, during the COVID-19 pandemic, all selected patients were contacted by telephone. An online or printed template of the previously validated Italian version of the COMQ-12 questionnaire [8] was addressed, together with a written agreement, to those who had given their oral consent by telephone. One hundred and forty-six replies were received by the same modalities. A power analysis confirmed that the number of respondents was adequate for a significant statistical analysis.

The COMQ-12 is a 12-item questionnaire, divided in 4 different categories: severity of symptoms, specific impact on work and lifestyle, impact on the health service and general impact of the disease on the patient. Based on the degree of

inconvenience or frequency of symptoms, each question is scored on a six-point scale from 0 (no impact or sporadic occurrence) to 5 (most severe impact or daily occurrence). Thus, the total score (range 0-60) was calculated for each case by adding the single answer scores (COMQ-12_tot). In addition, to facilitate the connection with surgical outcomes, we calculated three subscores: COMQ-12_disease activity from the sum of the scores of Q1, Q2 and Q5, COMQ-12_functional from the sum of Q3, Q4, Q6 and Q7, and COMQ-12_daily life impact from the sum of Q8, Q9, Q10, Q11 and Q12.

Statistical analysis

Categorical or dichotomous variables were expressed as absolute number and percentage (N, %). Continuous variables were expressed as mean ± standard deviation (μ ± SD). Chi-square or Fisher's exact tests and Mann-Whitney test were used to compare categorical and continuous variables, respectively, in the two groups of patients. Mixed effect models were used to assess the postoperative and long-term changes in terms of ABG between the two groups of interest (CWUT and CWDT). Pearson correlation coefficient was used for the comparison between independent continuous variables. A p-value < 0.05 was considered statistically significant. The software R (version 3.5.2) was used for statistical analysis.

Results

We received 146 questionnaire replies from a total of 137 patients. The power analysis showed that the study had a power of 85% to detect an effect size of 0.5 in terms of COMQ-12 scores between the two groups, at 5% alpha level using two-tailed test.

The mean age at the time of the surgery was 40 years (range = 7-79; SD 20.5) and the male/female ratio was 1.49 (82 males and 55 females). Sixty-eight procedures were classified as CWUT and 78 as CWDT with obliteration. Two patients had undergone both the procedures in the two ears. One patient in the CWUT group and 6 in the CWDT group were operated with the same procedure on both ears. In the CWUT group, the mean age was 33.9 years (range = 7-73) and the male/female ratio was 1.68 (42 males and 25 females). In the CWDT group, the mean age was 46.2 years (range = 8-79) and the male/female ratio was 1.4 (42 males and 30 females).

The mean clinical follow-up was 65 months (range 6-136), while the mean time between the last surgery and the survey reply was 83.1 months (range 30-138).

Residual cholesteatoma occurred in 12 patients treated by CWUT (17.6%) and in 5 treated by CWDT (6.4%) (p = 0.035); recurrent cholesteatoma was recorded in 6 cases in the CWUT group (8.8%) and in no case in the CWDT group (0%) (p = 0.009); other long-term anatomical complications, such as tympanic membrane retraction or lateralisation, granulations, or serous otitis media, had occurred in 9 patients (13.2%) treated by CWUT and in 10 (12.8%) treated by CWDT (p = 0.941). All patients who developed recurrent cholesteatoma had previously undergone a CWUT with mastoidectomy and were treated by revision mastoidectomy and CWDT.

Table I reports the hearing results obtained in the two groups at 6 weeks after surgery and at the last clinical follow-up. A significant postoperative change of PTA_{BC} was found in the CWDT group (p = 0.014), but not in the CWUT group. Nevertheless, the Delta-BC was not significantly different in the two techniques (p = 0.18). A significant postoperative improvement in PTA_{AC} was recorded in the CWUT group (p = 0.003), but not in CWDT patients. The difference between the mean postoperative AC and BC PTA in the two groups was statistically significant (p < 0.05). Preoperative ABG was not different between the two groups, while the 6-week postoperative ABG was 21 ± 12.2 dB and 25.2 ± 14.6 dB, respectively, in the CWUT and CWDT group (p = 0.046).

At long-term follow-up, the mean ABG was not different between the two groups. Conductive hearing loss was stable over time in the CWDT group (p = 0.29), while in the CWUT group a deterioration of the mean ABG was recorded at the last follow-up (27.0 ± 12.9 dB) in comparison to the early postoperative period (21.0 ± 12.2 dB) (p = 0.002).

The mean scores (± standard deviation) of each question in the two groups are reported in Table II, together with the total COMQ-12 score and the aggregate scores for disease activity, functional and daily life impact questions. Statistical analysis did not show a significant difference between the two groups, except for question 6, given that patients treated by CWDT complained of a greater impact of dizziness on their quality of life compared to CWUT patients (0.51 vs 0.21). Moreover, it should be noted that, regardless of the surgical technique, the highest scores were recorded in Q3 ("hearing at home"), Q4 ("hearing in groups") and Q12 ("general well being").

Table III shows the rates of response to each question. The percentage of patients for whom the postoperative ear condition heavily impacted in daily activities (Q8, answer 5, "Most days in the week") was 14.1% in the CWD group *versus* 5.9% in the CWU group. Similarly, in 6.4% of patients who had undergone a CWD technique water exposure had frequent repercussions in lifestyle (Q9, answer 5, "Most days in the week"), *versus* 1.5% of patients in the CWUT group. Finally, 9% (vs. 5.9% CWU) of patients

Table I. Hearing outcomes in the CWU and CWD groups.

	CWU	CWD	p-value (CWU *vs* CWD)
Pre-op PTA_{BC} ($\mu \pm SD$)	20.7 ± 13.1	23.9 ± 13.7	0.13
Post-op PTA_{BC} ($\mu \pm SD$)	21.1 ± 11.7	28.6±18.0	**0.01**
p-value (pre- *vs* post-op)	0.53	**0.014**	
Delta-BC PTA ($\mu \pm SD$)	-0.9 ± 7.5	-5.5 ± 15.6	0.18
Pre-op PTA_{AC} ($\mu \pm SD$)	48.6 ± 19.1	51.8 ± 21.5	0.41
Post-op PTA_{AC} ($\mu \pm SD$)	42.1 ± 17.7	53.5 ± 24.9	**0.008**
Last PTA_{AC} ($\mu \pm SD$)	50.2 ± 19.6	52.1 ± 24.0	0.954
p-value (pre- *vs* post-op)	**0.003**	0.74	
p-value (post-op *vs* last)	**0.001**	0.121	
Pre-op ABG ($\mu \pm SD$)	27.9 ± 13.3	27.9 ± 12.2	0.82
Post-op ABG ($\mu \pm SD$)	21.0 ± 12.2	25.2 ± 14.6	**0.046**
Last ABG ($\mu \pm SD$)	27.0 ± 12.9	25.5 ± 13.4	0.52
p-value (pre- *vs* post-op)	**0.001**	0.067	
p-value (post-op *vs* last)	**0.002**	0.294	
ABG Gain $\mu \pm SD$)	6.9 ± 14.5	2.9 ± 12.3	0.15

PTA_{BC}: bone conduction Pure Tone Average; PTA_{AC}: air conduction Pure Tone Average; ABG: Air-Bone Gap; CWU: Canal Wall-Up; CWD: Canal Wall-Down; μ: mean; SD: standard deviation.

Table II. COMQ-12 single questions, partial and total scores in CWU and CWD groups.

Question / Score	$\mu \pm SD$		p-value
	CWU	CWD	
Q1 ("Ear discharge")	0.47 ± 1.04	0.27 ± 0.73	0.352
Q2 ("Ear odour")	0.38 ± 1.06	0.19 ± 0.63	0.653
Q3 ("Hearing at home")	1.44 ± 1.46	1.46 ± 1.42	0.863
Q4 ("Hearing in groups")	1.56 ± 1.57	1.58 ± 1.34	0.616
Q5 ("Ear discomfort")	0.28 ± 0.84	0.18 ± 0.68	0.721
Q6 ("Dizziness")	0.21 ± 0.68	0.51 ± 1.11	**0.026**
Q7 ("Tinnitus")	0.60 ± 1.22	0.78 ± 1.18	0.134
Q8 ("Daily activities")	0.85 ± 1.53	1.06 ± 1.85	0.938
Q9 ("Water exposure")	0.63 ± 1.31	0.77 ± 1.50	0.584
Q10 ("GP attendance")	0.32 ± 0.74	0.18 ± 0.48	0.288
Q11 ("Drug requirements")	0.15 ± 0.55	0.10 ± 0.38	0.810
Q12 ("General well being")	1.62 ± 1.68	1.97 ± 1.63	0.133
COMQ-12_Disease activity	1.1 ± 2.4	0.6 ± 1.8	0.2928
COMQ-12_Functional	3.8 ± 3.5	4.3±3.6	0.2952
COMQ-12_Daily life impact	3.6 ± 3.7	4.1 ± 3.6	0.3282
COMQ-12_tot	8.5 ± 7.6	9.1 ± 7.3	0.4708

CWU: Canal Wall-Up; CWD: Canal Wall-Down; μ: mean; SD: standard deviation.

submitted to a CWD procedure felt that their ear problem gets them down (Q12). All other questions showed overlapping distributions.

Correlation analysis between total and aggregate COMQ-12 scores and postoperative ABG did not show any significant association in the CWDT group. Instead, in the CWUT group, a significant direct association between the postoperative ABG and both the COMQ-12 total score and functional subscore, with an increase of 0.17 (95% CI [0.03, 0.32], p = 0.019) and 0.01 (95% CI [0.02, 0.15], p = 0.014) in COMQ-12 total and functional scores respectively, for every unit increase in the postoperative ABG.

Table III. Questionnaire response rates in the CWU and CWD groups.

Question/Score	%											
	CWU						CWD					
	0	1	2	3	4	5	0	1	2	3	4	5
Q1 ("Ear discharge")	77.9	8.8	4.4	7.4	0.0	1.5	83.3	11.5	1.3	2.6	1.3	0.0
Q2 ("Ear odour")	86.8	1.5	2.9	5.9	1.5	1.5	88.5	6.4	3.8	0.0	1.3	0.0
Q3 ("Hearing at home")	36.8	22.1	16.2	11.8	11.8	1.5	34.6	21.8	20.5	10.3	11.5	1.3
Q4 ("Hearing in groups")	38.2	16.2	16.2	13.2	13.2	2.9	23.1	33.3	21.8	7.7	12.8	1.3
Q5 ("Ear discomfort")	88.2	2.9	2.9	4.4	1.5	0.0	89.7	6.4	2.6	0.0	0.0	1.3
Q6 ("Dizziness")	89.7	4.4	1.5	4.4	0.0	0.0	75.6	11.5	3.8	6.4	0.0	2.6
Q7 ("Tinnitus")	75.0	7.4	7.4	4.4	4.4	1.5	60.3	17.9	10.3	6.4	5.1	0.0
Q8 ("Daily activities")	67.6	11.8	5.9	2.9	5.9	5.9	69.2	7.7	1.3	5.1	2.6	14.1
Q9 ("Water exposure")	73.5	13.2	1.5	1.5	8.8	1.5	70.5	12.8	3.8	1.3	5.1	6.4
Q10 ("GP attendance")	79.4	13.2	2.9	4.4	0.0	0.0	85.9	10.3	3.8	0.0	0.0	0.0
Q11 ("Drug requirements")	91.2	5.9	0.0	2.9	0.0	0.0	92.3	5.1	2.6	0.0	0.0	0.0
Q12 ("General well being")	38.2	17.6	14.7	8.8	14.7	5.9	26.9	15.4	19.2	19.2	10.3	9.0

CWU: Canal Wall-Up; CWD: Canal Wall-Down; %: percentage.

Discussion

The surgical treatment of cholesteatoma aims at complete eradication of the disease, creation of a safe and dry external ear and, when possible, maintenance or restoration of conductive hearing.

CWUT, CWDT and radical mastoidectomies are the three main techniques used to treat cholesteatoma and the effectiveness of each has been traditionally evaluated by recidivism, rate and postoperative hearing function. The concept of health-related QoL has gained increasing interest in the last decades in all fields of otolaryngology and several questionnaires have been proposed and validated to measure the QoL in patients affected by chronic middle ear disease [3-6]. The use of these patient-reported outcome measures, together with the recidivism rate and hearing function, may help to better evaluate the results of different surgical techniques.

It has been shown by several authors that CWDT procedures are associated with a lower risk of residual cholesteatoma since they allow a better exposure of the middle ear and, in particular, of hidden anatomical regions such as the anterior epitympanic space and the posterior mesotympanum, while exteriorisation of the mastoid and epitympanic space reduces the risk of recurrent cholesteatoma [1]. The presence of a large mastoid cavity has, however, been associated with frequent debris accumulation and discharge, vertigo induced by sudden temperature changes in the EAC and difficulty in hearing aid fitting [1,2]; therefore, a modification of the standard technique by the introduction of mastoid obliteration has been proposed to overcome these problems [2]. In the present series, at long term-follow-up, residual and recurrent cholesteatoma rates were higher in CWUT; in fact, 8.8% of patients developed recurrent cholesteatoma and were submitted to revision CWDT.

Other authors have compared postoperative QoL of patients submitted to tympanoplasty for cholesteatoma. Lucidi et al. [10] compared CWDT without mastoid obliteration with CWUT by two different QoL questionnaires, namely the Chronic Ear Survey (CES) and Chronic Otitis Media Outcome Test 15 (COMOT-15). CWDT patients showed significantly lower symptoms subscale score of the CES at 3 months of follow-up, with the difference not being significant at 12-month follow-up. The authors explained this finding by the delayed healing of the surgical cavity in CWD patients, exposing them to water restrictions, frequent postoperative medical examinations and a higher risk of early postoperative otorrhoea. The analysis of the COMOT-15 administered at 12 months after surgery showed that CWDT patients reported significantly lower scores in the "hearing function" subsection that were confirmed by the significantly higher postoperative PTA of the CWDT group.

Lailach et al. [13], using the COMOT-15, did not show any significant difference in postoperative QoL for three different surgical techniques (transcanal tympanoplasty, CWUT and CWDT with obliteration), but demonstrated that "hearing function" was the most impaired domain in all patients. The COMOT-15, as reported by the same authors, does not however evaluate activity restriction in detail, in contrast to CES or COMQ-12, and therefore does not evaluate all the domains of QoL of these patients.

Our group has previously shown, using the CES questionnaire, that postoperative QoL was not significantly different after CWUT and CWDT with obliteration [9] and has attributed these results to the obliteration of the mastoid bowl that, by reducing the size of the cavity, diminished the problems associated with large open cavities. However, symptoms such as dizziness and tinnitus were not evaluated by the CES.

In the present study we showed, by the use of COMQ-12, that CWDT with mastoid obliteration is associated with good QoL even at long-term follow-up, that is not significantly different from CWUT. The only question where we found a significant difference was related to the impact of dizziness that was higher in the CWDT group; however, the low mean score (0.51 ± 1.11) underlines the minimal impact of this symptom on the QoL, as also reported by other authors after mastoid obliteration [14]. Despite the low prevalence of dizziness, the thermal labyrinthine stimulation can explain this finding, especially in case of long-term resorption of the bone dust.

Baetens et al. [15] evaluated the QoL in a group of patients undergoing CWUT with mastoid bony obliteration by the COMQ-12. Although the technique implies the total obliteration of the mastoid cavity and maintenance of the posterior canal wall, the authors reported a postoperative average score of 9.38 ± 7.73 which is very similar to our results (8.5 ± 7.6 in CWU and 9.1 ± 7.3 in CWD) and found that the most affected domains were "hearing at home" (Q3) and "hearing in groups" (Q4). Also in the present series, we found that Q3 and Q4 scores had the highest values in both groups. A significant positive correlation between COMQ-12 scores and postoperative ABG was evident in the CWUT group, in which for every dB there was an increase of 0.17 and 0.01 of the total and functional scores, respectively. Postoperative hearing loss remains the most important factor impairing QoL in cholesteatoma patients regardless of the technique used.

This study presents some limitations. First of all, we analysed the QoL of a sample of patients who were retrospectively selected from an electronic database; the mixed nature of the data collection, together with the limited size of the population and the inevitable lack in randomisation may bias the results. Moreover, a comparison between preoperative and postoperative QoL was not possible, since we had not collected questionnaires at the time of the surgery. Finally, QoL results were collected at an extremely variable postoperative time.

Despite these limitations, we believe that this study has several strengths. First, this is the first study comparing CWUT and CWDT with obliteration using the COMQ-12, a questionnaire that evaluates the QoL of patients in terms of disease activity, functional impairment and general impact on the life such as long-term GP attendance and medical treatments needed. In fact, the utility of the COMQ-12 in the evaluation of QoL of patients affected by middle ear disease has been recently demonstrated by a multinational collaboration [16,17]. In addition, in the present study the scores of the COMQ-12 questionnaire were correlated with the anatomical and functional results, demonstrating a strict relationship between the ABG and total and functional score of the COMQ-12.

Conclusions

This study confirms that CWDT procedures with mastoid obliteration lead to similar results in terms of QoL compared to CWUT techniques. Hearing loss remains the most important post-operative complaint of these patients. Nevertheless, the overlapping results in terms of QoL and the significantly lower rates of residual and recurrent cholesteatoma, suggest that CWDT with obliteration is a good alternative to CWUT when indicated.

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Conflict of interest statement

The authors declare no conflict of interest.

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Authors' contributions

VP and NQ have developed the study design, created the database, collected the data and equally contributed to the writing of the manuscript. MD, AH and MS have partecipated in data collection. GG has performed the statistical analysis.

Ethical consideration

The study was approved by the local Ethics Committee of Policlinico di Bari (PROT 4799/2019) and carried out in accordance with the Declaration of Helsinki. All patients received appropriate and comprehensible information about the study, the surgical procedures and tests, and gave their written consent.

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