

Sinonasal Inverted Papilloma and predictors of Health-Related Quality of Life after Endonasal Endoscopic Surgery: a prospective cohort study

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Abstract

Objectives: Existing knowledge on Health Related Quality of Life (HRQoL) after surgical removal of sinonasal inverted papilloma (IP) is limited. Moreover, predictors for a better or worse postoperative HRQoL outcome are not known. Our aim was to assess HRQoL in all three health domains (physical, psychological and social), track its postoperative trajectory, investigate if preoperative observations could predict distinct postoperative HRQoL outcomes, and evaluate whether physicians' interventions could contribute to improved postoperative HRQoL. **Design:** Prospective cohort study. **Setting:** Tertiary referral hospital. **Participants:** Seventy-four patients who underwent surgery for an IP were included. They were asked to fill in the Endonasal Endoscopic Sinus and Skull Base Surgery Questionnaire (EES-Q) preoperatively, and then two weeks, three months, and one year postoperatively. **Main outcome measures:** Linear mixed models (LMM) analyses were performed to evaluate the overall postoperative HRQoL and the separate health domains, as well as the impact of specific variables (sex, age, ASA classification, smoker, Krouse staging, preoperative EES-Q score, type of surgery and postoperative antibiotics) on HRQoL improvement. **Results:** The total EES-Q score ($P < .001$) as well as the physical ($P < .001$), psychological ($P = .049$), and the social ($P = .002$) domains significantly improved postoperatively. ASA classification ($P = .049$), preoperative EES-Q score ($P < .001$) and postoperative antibiotics ($P = .036$) were significant variables. **Conclusions:** Overall HRQoL, as well as each of the three health domains, improved significantly. A higher ASA score, a higher preoperative EES-Q score, and the administration of postoperative antibiotics were significant predictors for better HRQoL recovery postoperatively. Further research is necessary to confirm these results.

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KEYWORDS

Sinonasal inverted papilloma, EES-Q, health related quality of life, patient-reported outcome measure, prospective cohort study.

KEYPOINTS

- To date, only few studies examined the Health Related Quality of Life (HRQoL) in patients with an sinonasal inverted papilloma (IP). Moreover this is mainly limited to the physical domain.
- The endoscopic endonasal sinus and skull base surgery questionnaire (EES-Q) does assess all three health domains: physical, psychological, and social.
- Postoperatively, we observed a temporary decline in HRQoL, primarily attributed to patients' social limitations, but over the total examined postoperative period, all three health domains and consequently, the overall HRQoL significantly improved.
- We found that a higher ASA score, a higher preoperative EES-Q score, and the administration of postoperative antibiotics were significant predictors for better HRQoL recovery postoperatively.

INTRODUCTION

Sinonasal inverted papillomas (IP) are benign tumours accounting for 0.4% to 7% of all tumours of the sinonasal tract.¹ It primarily affects patients in their fifth to sixth decades of life, with a male to female ratio ranging from 2 to 3:1. While they can occur across a wide range of ages, these conditions are generally rare in children.² Despite the benign character there are three main reasons to remove the tumour. First, there is a risk of malignant transformation.³ Second, because of the clinical presentation of the patients.⁴ And last, aggressive growth can lead to the destruction of local anatomical structures.⁵ After surgery, patients will need to recover physically, process the event psychologically and gradually restart their daily activities. These factors can have a major impact on patients' health related quality of life (HRQoL).

To date, only few studies examined the HRQoL in patients with an IP. These studies found that patients with a benign sinonasal tumour have a better postoperative HRQoL compared to those with a malignant tumor. They also found that the HRQoL returned to normal after surgical removal of an IP.⁶⁻⁸ However, this has not been explored with the Endonasal Endoscopic sinus and skull base Surgery Questionnaire (EES-Q), which has the three obligate health domains (physical, psychological and social), but mainly in the physical health domain. Moreover, predictors for a better or worse postoperative HRQoL outcome are not known.

Because there is an increasing need to comprehensively evaluate the effects of diseases and treatment, the objectives of our study were threefold. First, we aimed to assess the preoperative HRQoL and subsequently examined the postoperative trajectory. Second, we sought to investigate whether preoperative observations can serve as predictors for distinct postoperative HRQoL outcomes. Additionally, we aimed to evaluate

whether interventions carried out by physicians can contribute to improved postoperative HRQoL. By achieving these objectives, we hope to enhance the counselling process for patients with IP and gain novel insights into the outcome of actions performed by the physician.

MATERIALS AND METHODS

1. Ethical considerations

The study was authorized by the local institutional ethical review board of our tertiary referral center.

2. Inclusion

Patients undergoing surgery for an IP at our department of Otorhinolaryngology – Head and Neck Surgery were asked to participate in this study if they met the inclusion criteria.

These criteria were: 1) endoscopic endonasal surgery for a histologically proven inverted papilloma; 2) [?]18 years old; 3) capable of reading and writing in Dutch language.

After informed consent, patients received the Endonasal Endoscopic sinus and skull base Surgery Questionnaire (EES-Q) by (e-)mail and were asked to complete the questionnaire preoperatively, and then at two weeks, three months, and one year postoperatively. These questionnaire moments coincided with the regular controls in the outpatient clinic.

A preoperative EES-Q and at least one follow-up EES-Q were prerequisites for data analysis.

3. Surgical techniques

Patients underwent endonasal endoscopic surgery by a skilled surgeon in a tertiary care center. Depending on the tumour location and extension different surgical procedures were performed. All procedures were carried out with image-guided surgical navigation (Kick® EM, Brainlab, Heimstetten, Germany).

As most inverted papillomas grow into the maxillary sinus, most interventions consist of a modified endoscopic Denker's procedure.⁹

In this study we distinguish in our modified endoscopic Denker's procedures between a medial maxillectomy type 2 and type 3.

With a tumour outside of the maxillary sinus, endoscopic excision with or without functional endoscopic sinus surgery (FESS) was performed.

4. Design of the study

In this prospective cohort study we used the EES-Q as the HRQoL instrument. This is a validated instrument for assessing the HRQoL in all three health domains (physical, psychological and social) during the surgery period.^{10, 11} A total of 30 items (10 per domain) describe activities or complaints with a 5-point Likert response scale ranging from not at all (1), (mildly (2), moderately (3), severely (4)) to very severely (5) to indicate the degree of inconvenience. Note that higher scores correspond with lower HRQoL.

4.1 EES-Q score and domain scores

To obtain an easily interpretable score, the sum of scores in one domain were recalculated into a *domain score* ranging from 0 (not at all) to 100 (very severe inconvenience). *Domain scores* were calculated by summing the 10-item score of each domain, subtracting 10 points from this total and multiply this by 2.5. *Domain scores* were corrected for the missing answers by adjusting the subtracted value and the multiplication factor accordingly.¹¹ The maximum number of missing answers was three per subject per domain, otherwise it was filed as missing data. The *EES-Q score*, ranging from 0 (not at all) to 100 (very severe inconvenience), was calculated by summing the three *domain scores* and dividing the total score by three.

4.2 Variables

Data on *sex* and *age* were collected by the medical records.

The extension of tumour was defined by preoperative *Krouse staging* ,¹² see table 1.

Comorbidity of the patients was defined by the American Society of Anaesthesiologists (ASA) classification, ranging from *ASA 1* to *ASA 6* .¹³ *Smoking* was added as separate variable.

To assess whether the preoperative EES-Q score could be a predictor for postoperative HRQoL, three equal groups were made based on the preoperative EES-Q score. These were obtained by the 33 1/3 and 66 2/3 percentile of the preoperative scores. These groups were defined as *low preoperative EES-Q score* , *middle preoperative EES-Q score* and *high preoperative EES-Q score* .

Surgical procedures (as mentioned above) were defined as *medial maxillectomy type 2* , *medial maxillectomy type 3* and *other* .

If patients had postobstructive sinusitis, they were given oral antibiotics following surgery. We examined the effect of *postoperative antibiotics* on the postoperative HRQoL.

5. Statistical analysis

Descriptive statistics were used to describe patient characteristics. Mean EES-Q score and mean domain scores were calculated. To examine if there was a relationship between the *preoperative EES-Q score* and the other variables a descriptive exploratory analysis (Pearson's chi-square) was performed.

5.1 Linear Mixed Models

To assess the HRQoL outcome we performed linear mixed models (LMM) analyses on our data.

The course in *time* was adjusted for the irregularly spaced postoperative surveys and squared if this resulted in a better model of fit. To determine best model of fit -2 Log Likelihood (-2LL), Akaike's Information Criterion (AIC) and Schwarz's Bayesian Criterion (BIC) were used.

For the analysis on predictors the variables *sex*, *age*, *Krouse staging*, *ASA*, *smoker*, *preoperative EES-Q score*, *type of surgery* and *postoperative antibiotics* were included as fixed effects. The variable *age* was mean-centered.

Covariance type was set at *unstructured* and calculation was based on *repeated measures* . This was also determined by using -2LL, AIC and BIC. Estimation method was set to *maximum likelihood* . Coefficient, standard error, 95% confidence interval and p-value are displayed.

All statistical analyses were performed with IBM SPSS Statistics version 22.0 (SPSS IBM, Inc., Armonk NY, USA).

RESULTS

3. Baseline characteristics and treatment

A total of 74 patients were enrolled in this study. Mean age was 60 years and 69% was male. Baseline characteristics and treatment are presented in table 2.

Mean follow-up was 3.2 years. In this population no patients had a malignant transformation of the tumour.

In five patients there was a small defect of the lamina papyracea (with the peri-orbit still intact) and in two patients there was a small cribriform plate defect without liquorrhea. All other procedures were without complications.

Postoperatively, one patient experienced bleeding, which was successfully treated with a tamponade. Another patient had bleeding that eventually required unilateral clipping of the sphenopalatine artery. Additionally, two patients developed infected wound beds in the postoperative period, which required oral antibiotic treatment.

2. EES-Q score and domain scores

Results of the LMM are shown in table 3. Mean EES-Q scores and mean domain scores were plotted in a graph (figure 1).

3. Variables and HRQoL

The cut-off values for the 33 1/3 and 66 2/3 percentiles of the preoperative EES-Q scores were 12 and 26, respectively.

LMM results of the variables and the postoperative HRQoL are shown in table 4 and the mean ESS-Q scores for the different groups of the variables are plotted in a graph (figure 2 and 3).

In exploratory analysis we found no significant correlation between the preoperative EES-Q score and the other variables (table 5). In this analysis age was dichotomised by the median (63 years).

DISCUSSION

To our knowledge this is the first prospective cohort study examining the health related quality of life (HRQoL) in all three health domains in patients undergoing surgery for a sinonasal inverted papilloma (IP). Besides, it is the first study seeking predictors for a more complete HRQoL outcome in this population.

Key findings

Due to the social complaints, there is a remarkable decline in HRQoL 2 weeks postoperative. Eventually, patients will have a significant improvement in their HRQoL 3 months and 1 year postoperatively.

We found that a higher ASA score, a higher preoperative EES-Q score and the use of postoperative antibiotics resulted in a more distinct improvement of postoperative HRQoL. Tumour extent was not a significant predictor of postoperative HRQoL. Neither was surgical invasiveness, nor the other measured variables.

These results may lead the surgeon to discuss these issues preoperatively. Moreover, it suggests a better healing process with postoperative antibiotics. Lastly, it questions whether surgical conservatism should be pursued indiscriminately in this disease, as we do not measure a difference in HRQoL outcome.

Comparison to other studies

Our IP cohort has a better preoperative HRQoL compared to the preoperative HRQoL of the chronic rhinosinusitis (CRS) patients from our recently published study.¹⁴ The CRS patients had a mean EES-Q score of 37 (only median scores are published); in this population the mean preoperative score was 20. The biggest difference was in the physical domain, followed by the social domain. Our IP cohort does have a worse HRQoL than the healthy individuals of that same study (20 vs 14, respectively). The EES-Q score of the IP cohort one year postoperatively is similar to the EES-Q score of healthy individuals, suggesting that HRQoL will return to normal. Van Samkar and Georgalas support this outcome by showing that the SNOT-22 score after removal of an IP at follow-up (median 6 years) is similar as in healthy individuals.⁸ Whether the social domain was influential in their outcome is not known because the SNOT-22 cannot differentiate between these, unlike the EES-Q. In addition, they had no preoperative data and their population was rather small (n=37). Deckard et al. included 18 IP in their analysis on HRQoL after endoscopic treatment of sinonasal neoplasms (n=71) and concluded that patients with benign tumours have a better HRQoL outcome than patients with malignant tumours.⁶ Harrow et al. reported similar results in their study including IP patients (n=19), who accounted for only 20% of their total population (benign and malignant).⁷ Both performed no subanalysis on IP alone.

Preoperatively, patients of the different ASA groups score similar. However, the postoperative HRQoL is better in patients with a higher ASA score. We hypothesize that this can be explained by the fact that chronically diseased patients are known to accommodate to their illness, which results in better HRQoL measures.¹⁵ Moreover, the group with the high preoperative EES-Q score show the biggest improvement in HRQoL postoperative compared to the other groups. This is in line with CRS studies where patients with a higher preoperative SNOT-22 score show a greater improvement postoperative compared to patients with a lower preoperative SNOT-22 score.¹⁶⁻¹⁸

The existing body of literature presents divergent findings regarding the benefits of postoperative antibiotics after endoscopic endonasal sinus (EES) surgery for sinusitis. While certain studies demonstrate positive outcomes associated with their use,¹⁹⁻²¹ other studies do not report significant advantages.^{22, 23} Systematic reviews on this topic therefore do not provide a comprehensive recommendation.^{24, 25} In our cohort, antibiotics were administered for the treatment of postobstructive sinusitis, i.e. secondary sinusitis. Notably, the forementioned studies do not differentiate between primary and secondary sinusitis, although this distinction could potentially influence the outcome. To the best of our knowledge, there are no existing studies investigating the use of postoperative antibiotics specifically for secondary CRS. Our hypothesis is that if antibiotics contribute to improved long-term HRQoL, it may be attributed to enhanced healing of the sinonasal mucosa. Further research is necessary to explore this in greater detail.

Strengths and limitations

Since IP is a relatively rare disease, research in this field with a big cohort is a big challenge. Nevertheless, our cohort appears to be relatively large compared to the other clinical IP studies. For more support of evidence of our results, more studies (with greater numbers) should be performed. Furthermore, the retrospective nature of the intervention analyses does not provide conclusive evidence for the future. Lastly, to date there is no minimal clinically important difference (MCID) known of the EES-Q.

Future perspectives

First, we want to examine whether patients who received postoperative antibiotics maintain a higher level of HRQoL in comparison to the non-antibiotics group. To accomplish this, we will administer the EES-Q questionnaire once again, five years after the surgical intervention.

Second, it is our goal to determine the MCID of the EES-Q for better interpretation of the results.

Third, there is no significant difference in HRQoL between patients who underwent a median maxillectomy 2 (MMT) and those who underwent a MMT 3 procedure. The assessment of long-term recurrence was not within the scope of this study. Exploring the potential association between surgical invasiveness and recurrent rates of IP offers a valuable subject for future research.

Last, there is a growing trend to thoroughly assess the impact of diseases and treatment. We therefore ask all our patients who undergo endoscopic endonasal sinus and/or anterior skull base surgery to contribute to our research by filling in the EES-Q at predetermined times. We aspire to use questionnaires for patient monitoring, disease screening, counselling for treatment and for clear communication between the physician and the patient.

CONCLUSION

In this first prospective cohort study on HRQoL after surgical removal of a sinonasal inverted papilloma, we observed a temporary decline in HRQoL shortly after the surgery, primarily attributed to the social limitations encountered by patients. In the total examined postoperative period, all three health domains, and consequently, the overall HRQoL improved significantly. Moreover, we found that a higher ASA score, a higher preoperative EES-Q score, and the administration of postoperative antibiotics were significant predictors for better HRQoL recovery postoperatively. Further research is necessary to confirm these results.

LIST OF TABLES AND FIGURES

Table 1 Krouse staging for inverted papilloma

Table 2 Patient characteristics and treatment.

Table 3 linear mixed models of the EES-Q score and domain scores separately.

Table 4 linear mixed models of the EES-Q score with the variables.

Table 5 Pearson chi square, P-value.

Figure 1 Mean EES-Q and mean domain scores.

Figure 2 preoperative observations.

Figure 3 Interventions.

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Figure 1 Mean EES-Q and mean domain scores.docx available at <https://authorea.com/users/640225/articles/655184-sinonasal-inverted-papilloma-and-predictors-of-health-related-quality-of-life-after-endonasal-endoscopic-surgery-a-prospective-cohort-study>

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