Does Compliance with Swallowing Exercise Regimes Impact Swallowing Outcomes in Head and Neck Cancer Patients?

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Background: The prevalence of HPV-head and neck cancer (HNC) is increasing over the past 20 years. Fortunately, patients with HPV HNC have better survival rates than other HNCs. This means that patients live with the impact of their treatments, which is often swallowing impairments or dysphagia. Patients get prescribed exercises to prevent swallowing impairment or improve their swallowing functions. The average adherence rate is below 50% and low adherence can make it difficult to examine the effectiveness of a treatment both clinically and empirically (Krekeler et al., 2018). It makes sense that patients who do not comply with their prescribed exercises may not benefit from the intervention – however this should be explore. **Objective:** We performed a critical review of the literature that associated compliance with exercise to swallowing outcomes. We then conducted our own retrospective chart review to add a Canadian perspective. **Results:** Compliance was primarily measured through self-report either verbally or through checklists. Although not supported by a Canadian small-scaled study, the critical analysis of the literature suggested that compliance with swallowing exercises was positively associated with swallowing outcomes: g-tube dependency, changes in diet, and self-reported quality of life related to physical aspects of swallowing. **Implications:** Clinicians should encourage patients to perform exercises. A standard method of measuring compliance and support for clinicians to track compliance is needed to gain insight into an effective dosage of exercise.

Introduction

Over 4000 Canadians will be diagnosed with head and neck cancer (HNC) this year and about 1000 among them will not survive (Canadian Society of Otolaryngology – Head & Neck Surgery, 2017). In the past 20 years, there has been in increase in human papilloma Virus (HPV) related HNC (Nichols et al., 2013). Fortunately, in this particular population the patients are younger, healthier, and tend to have better survival rates compared to HPV-negative HNC (Ang et al., 2010; O'Rorke et al., 2012). Unfortunately, this means that patients need to live with the impact of their treatment – surgery and/or radiation and chemotherapy (RT/CRT). A major symptom patients experience as a result of their treatment is swallowing impairments or dysphagia (Nguyen et al., 2004; Nguyen et al., 2006), which can develop years after the completion of their treatment (Hutcheson et al., 2012; Kraaijenga et al., 2015).

Patients often get prescribed exercises to prevent swallowing impairments or improve their swallowing abilities. Evidence suggests that these exercises can preserve muscle maintenance (Carnaby-Mann et al., 2012), limit swallowing impairments (Greco et al., 2018; Rodriguez et al., 2018), and improve quality of life (Kulbersh et al., 2006; Rodriguez et al., 2018). Compared to after treatment, exercises performed before and during treatment may lead to better swallowing function (Carroll et al., 2007), quality of life (Kulbersh et al., 2006;), and less g-tube dependence (Virani et al., 2015).

Contrarily, a large Cochrane review found no evidence that performing exercises before, during, or after treatment leads to improvement in swallowing (Perry et al., 2016). The researchers spoke to small sample sizes in the clinical trials and lack of power to find significant effects. However the patients' adherence with exercises may have also diminished the effects of the therapeutic exercises.

The average adherence rate across 12 studies (nine were HNC related) that tracked patients' compliance averaged between 21.9-51.9% (Krekeler et al. 2018). Not many studies reported compliance or took compliance into consideration in their analysis. Low adherence can make it difficult to examine the effectiveness of a treatment both clinically and empirically (Krekeler et al., 2018). Patients who do not comply with their clinicians' recommendations or prescribed exercises may not benefit from the intervention; however this should be explored.

Objectives

The primary objective of this paper was to critically evaluate the existing literature investigating the relationship between compliance with a swallowing exercise regime and swallowing outcomes in patients with HNC. A retrospective review of patients with HNC from a local hospital was then performed to add a Canadian perspective. The second objective was to gain some insight into how compliance with

exercises was measured in studies and in clinical settings.

Study One: Critical Review

Methods

Search Strategy

Search terms used in the computerized database PubMed, Scorpus, and PsychInfo included: ("deglutition disorders" OR dysphagia) AND (exercise) AND ("patient compliance") AND ("head and neck cancer") AND (outcome(s)). Please see Appendix 1 for the full list of search terms for each database. Additionally, the reference lists of previously searched articles were examined for additional articles.

Selection Criteria

A total of 23 articles were obtained by the search strategy and were further examined by reading the abstract or the full article. Studies selected to be included in this review were required to measure compliance with swallowing exercises in relation to swallowing outcomes in patients with head and neck cancer. Review articles and articles outlining future study protocols were excluded.

Data Collection

Results of the literature search that matched the selection criteria yielded four articles that retrospectively examined patient chart data (Bhayani et al., 2013; Duarte et al., 2013; Hutcheson et al., 2013; Krisciunas et al.) and one article that prospectively reviewed medical charts (Shinn et al., 2013).

Results

Retrospective Chart Review

A retrospective chart review is an appropriate design to examine the relationship between compliance to exercises and swallowing outcomes. However, there are limitations to analyzing compliance retrospectively – because compliance was not the main focus of chart notes, some information about patient compliance may not have been recorded, or the collection of compliance and the description of compliance could differ across providers.

Bhayani and colleagues (2013) examined the factors related to risk for, and prolonged use of (6 months or greater), gastrostomy tube (g-tube) placement in 474 patients from one cancer center. The factors were compliance to exercise, smoking history, sub site, t-stage, radiation type, baseline dysphagia, baseline weight loss – but only compliance is relevant to the current review. The researchers retrospectively reviewed the medical records of their patients and medical information regarding patient characteristics, disease, and treatment were abstracted. Information collected about the g-tube included type of g-tube, timing of placement, and amount of nutritional formula used per day.

Adherence with exercises was collected from the notes of the speech pathologist on the patients' charts, which detailed the patients' self-reported number of exercises performed per day. The researchers classified three levels of adherence: full adherence as performing exercises more than 4x/day, partial adherence 4x/day, and no adherence – but later combined participants into two adherence groups.

Results revealed that compliance was independently related to g-tube placement and prolonged g-tube dependence. Compliant patients were less likely to have a g-tube compared to non-compliant patients – who were more likely to have prolonged g-tube dependence.

Strengths of this study include a large sample size, multiple factors analyzed, and use of appropriate statistics. Limitations included: lack of detail regarding procedures and decisions – how data extraction was performed, if data was verified, and if the researchers met consensus, how and why the three levels of adherence were combined into two groups. The results have limited generalizability because the patients were all from one site. As well, the point of referral to SLP services was not considered (before, during or after RT treatment) in the analysis. This study provided highly suggestive evidence that adherence to swallowing exercises may prevent g-tube placement or decrease the length of g-tube dependence.

Duarte and colleagues (2013) examined the efficiency of a swallow preservation protocol (SPP) in maintaining swallowing function in 89 patients. The patients participating in the SPP performed the exercises before and during treatment. The researchers retrospectively extracted patients' weight loss, stenosis, aspiration, xerostomia, dysgeusia, odynophagia, and change in diet from the patients' medical charts and chart notes. The patients tracked their own adherence to exercises on a form, which was later reviewed by the researchers. Adherent patients were defined as performing at least 1 full set of exercises per day, and non-adherent patients as performing less than one full set of exercises per day.

Results indicated about two thirds of the sample adhered to the exercise protocol, with compliant patients being significantly more likely to have maintained a regular diet one month post rehabilitation. Furthermore, significantly more of the compliant patients maintained or improved their diet from pretreatment compared to the noncompliant patients. The compliant group also had a lower incidence of upper esophageal stenosis (measured via MBS 2 months following RT).

Strengths of the study included appropriate statistics, and demonstration of baseline equivalence between groups. Limitations include lack of detail in methods regarding measures of pain, aspiration, xerostomia, dysgeusia, odynophagia, and chart review, as well as a small sample size, and a short follow up.

Overall, the study provided suggestive evidence that complying with prophylactic swallowing protocols before and during RT/CRT therapy benefits swallowing outcomes, especially in maintaining a regular diet.

Hutcheson and colleagues (2013) investigated the independent effects of preserving an oral diet throughout RT or CRT treatment and adherence to a swallowing exercise regime on changes in diet in 497 patents from a single cancer center. Data abstraction from the patients' medical records included patients' diet at two follow up visits that occurred between 6-12 months and 18-24 months, as well as the patients' self-reported swallow exercise adherence. Adherence to exercises was defined as partial, less than 4 times a day, or full, 4 times a day or more. Patients who reported not performing the exercises or who did not attend their SLP appointment were defined as non-adherent.

Overall, 58% of the participants were adherent to the exercises. Maintaining oral intake and adherence to exercises were independently positively associated with a long-term regular diet (no restrictions of food or drink by mouth and no change in preparations of foods). Patients who adhered to exercise were four times more likely to return to a regular diet and adherence to exercise was associated with a shorter duration of g-tube dependence.

Strengths include large sample size, clear presentation of results, and independent analysis of eating and exercise. Limitations include lack of detail in data abstraction methods.

This study provides highly suggestive evidence that adhering to an exercise program can have positive outcomes related to diet and oral intake, and that these effects are independent of eating habits.

Krisciunas and collegues (2017) performed a secondary analysis on data obtained from a previous RCT that showed that electronic stimulation (e-stim) had negative effects on swallowing function. The researchers retrospectively investigated if compliance to exercise impacted their results. The variables measuring swallowing function were Penetration-Aspiration Scale (PAS), Performance Status Scale for Head and Neck Cancer Diet (PSS-HN DIET), Functional Oral Intake (FOIS), Oropharyngeal Swallowing Efficiency (OPSE), and hyoid excursion. Compliance with exercise data was abstracted from self-recorded daily logs, and grouped into adherent and non-adherent based on the average amount of daily exercise performed.

Following appropriate statistical analysis results showed that 54% of the participants adhered to the exercises and showed no difference in swallowing outcomes compared to those that did not adhere. When controlling for compliance of their participants, their results remained the same – e-stim had a negative impact on some of the swallowing variables.

Limitations include the cofounding variable of the e-stim device, relatively small sample size, and lack of detail in data extraction. Overall, the study provides suggestive evidence that complying with swallowing exercises may not improve swallowing outcomes; particularly after treatment is completed and if the patients are already experience symptoms.

Prospective Chart Review

Shinn and colleagues (2013) examined the association between compliance with swallowing exercises performed during treatment and long-term (1-2 years post treatment) swallowing quality of life measured by the MD Anderson Dysphagia Inventory (MDADI). The researchers also appropriately conducted structured phone interviews 6 months after treatment to discuss reason for non-adherence.

Adherence to exercises was recorded prospectively in an electronic medical record by the SLPs. The SLPs made judgments on patients' adherence – fully, partial, or non-adherent – based on their competency in performing all of the assigned swallowing exercise and by verbal report. Later the researchers collapsed the participants into two adherent groups.

Overall 45% of the patients were adherent to the exercises. Adherence to swallowing exercises was significantly associated with all three MDADI subscales, and independently associated with the MDADI physical subscale. The two most common reasons for not adhering to the exercises were lack of understanding of the importance of the exercise, and due to the side effects of treatment (e.g. pain, nausea, fatigue).

Limitations include: relatively small sample size, lack of detail in how and why adherent groups were collapsed, and lack of detail in statistical analysis. For example, it is not clear if they performed parametric or non-parametric statistics. They should have performed non-parametric due to the large differences in the group sizes. The strengths of the study include prospective recording of adherence and long-term follow-up of quality of life.

This study provided highly suggestive evidence that adhering to swallowing exercises during RT treatment positively impacts long-term swallowing-related quality of life.

Discussion

To summarize, four of the five studies provide evidence that compliance with swallowing exercise regimes is positively associated with swallowing outcomes. The participants in the study that did not show an association (Kriscuinas et al., 2017) were on average 3 months post-treatment and had moderate-to-severe dysphagia, while the other studies had participants who performed exercises before and during treatment. Prophylactic exercises may result in better outcomes compared to exercises after treatment (Carroll et al., 2017). Perhaps the participants in this study were too far advanced to experience benefits of the exercise. Furthermore, unlike the other studies, Kriscuinas and colleagues did not control for participants who had previous head and neck surgery, which can lead to more severe swallowing impairments.

All of the studies were performed in the United States and three studies (Bhayani et al., 2013; Hutcheson et al., 2013; Shinn et al., 2013) were all conducted at the MD Anderson Center in Texas. A Canadian perspective is needed.

Study Two: Retrospective Chart Review of Canadian Data

The following aimed to add a Canadian perspective to the compliance with exercise literature in regards to HNC by retrospectively analyzing charts of patients from a local Canadian hospital, which follows similar protocols to the MD Anderson Center.

Methods

We retrospectively reviewed the medical charts of patients treated with RT or CRT for pharyngeal HNC at Victoria Hospital in London, Ontario. This site follows a proactive swallowing therapy protocol similar to the MD Anderson Center (Hutcheson et al., 2013). Patients received an initial consultation before their treatment and are taught swallowing exercises, and also attended regular SLP visits during treatment. The patients' swallowing outcomes: Performance Status Scale for Head and Neck Cancer Diet (PSS-HN DIET; List et al., 1990), Functional Oral Intake (FOIS; Crary et al., 2005), and MD Anderson Dysphagia Inventory (MDADI Global; Chen et al., 2001) were measured 3, 6, and 12 months post-treatment.

A single researcher abstracted data from medical charts of 49 patients, including the swallowing outcomes, patient demographics, P16, cancer site, and SLP chart notes from visits, which documented patients' self-reported compliance with exercises. Eleven patients were excluded due to missing data or missed appointments. Two researchers independently examined the SLP chart notes and reached a consensus on if the participant had "high compliance" (daily adherence), "low compliance" (occasional or sometimes adherent), and no compliance. Participant characteristics are found in Table 1 in Appendix 2.

<u>Statistical Analysis</u>
We initially planned to compare the swallowing outcomes between three compliant groups, however our sample size did not allow for that analyses. Therefore, we grouped "low compliance" and "no compliance" participants together and compared their swallowing outcomes at 3 months, and 12 months for MDADI, to the "high compliance group" We used chi-square for categorical variables and independent sample Mann-Whitney t-test for continuous variables.

Results

There was no difference in age, gender, cancer site or P16 between the two groups (Table 1, Appendix 1). As shown in figure 1 the two groups, at 3 months post-treatment, did not differ in PSS (p= .919), FOIS

(p= .911), and MDADI (p= .767), or in the MDADI at 12 months (p= .902).

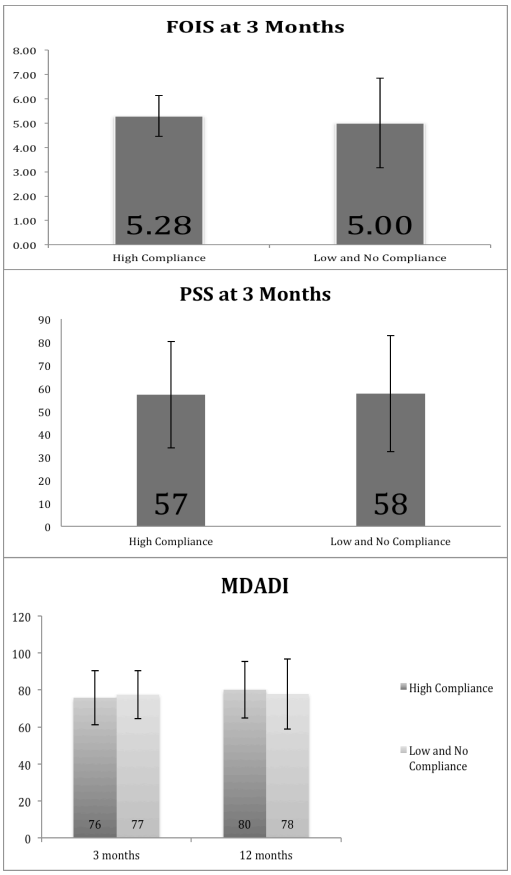

Figure 1. Swallowing outcomes between high compliance and low and no compliance at 3 months, and 12 months for MDADI.

Discussion

The results of the Canadian retrospective chart review suggest that compliance with swallowing exercises does not impact swallowing outcomes, which is inconsistent with the results of the critical review. Major shortcomings of the Canadian retrospective review were a very small sample size, missing data, and second hand notes on self-reported compliance that were not consistent across SLPs. Therefore the results should be interpreted with caution.

General Discussion

Although not supported by a Canadian small-scaled study, a critical analysis of the literature suggested that compliance with swallowing exercises is positively associated with swallowing outcomes – g-tube dependency, changes in diet, and self-reported quality of life related to physical aspects of swallowing. Therefore, the researches recommended clinicians to encourage patients to perform exercises as much as possible.

General limitation themes appeared across all studies. In the future, these should be considered in order to improve the quality of research and further add to the knowledge regarding compliance with exercises and it's association to swallowing outcomes.

Abstraction of chart data

Four of the studies lacked details in terms of how the researchers performed the chart review (Bhayani et al., 2013; Duarte et al., 2013; Hutcheson et al., 2013; Shinn et al., 2013). They did not report how they collapsed the compliance data across the clinical visits to get a final overall compliance rating. This is important information for replication and to judge their procedures.

Unfortunately, all five studies did not stipulate if more than one clinician reviewed the chart data and if there was a consensus about patients' assigned compliance group. This is an important step in retrospective reviews to ensure data was abstracted correctly. The researchers should be upfront about whether or not this was done.

Dichotomizing compliance data

All five of the articles grouped the patients into two groups – adherent vs. non-adherent. This is an appropriate method to create categorical variables from self-reported data. The patients' compliance was not systematically tracked, so it would be difficult to make the compliance rating a continuous variable. However three of the studies in their methods described that they classified the compliance data into three levels (fully adherent, partially adherent, non-adherent), but later for analysis collapsed the three levels into two (Bhayani et al., 2013; Hutcheson et al., 2013; Shinn et al., 2013). None of the studies described why they used two groups instead of three. It was possibly due to ease of statistically analysis, or perhaps the researchers first analyzed three groups and did not find significant results. Furthermore Bhayani and colleagues (2013) did not describe how they collapsed the groups together. This lack of detail and transparency makes the results somewhat questionable.

Grouping into two compliant groups can underestimate the relationship between compliance and swallowing outcomes. Instead, sub-grouping compliance into more than two groups could

demonstrate a dosage response and provide clearer insight to proper dosage. Krisciunas and collegues (2013) clearly outlined how they calculated an average number of exercise sessions performed per week from the self-reported therapy checklist. This ranged from 0-12 sessions. They classified 10 or more as adherent and less then 10 as non-adherent. The researchers instead could have treated the average number of sessions as a continuous variable in their data analysis, which would have yielded in a more detailed understanding of the relationship between compliance and swallowing outcomes.

Measuring compliance

Two of the five studies relied on patients' verbal self-report of compliance that was documented in their medical charts (Bhayani et al., 2013; Hutcheson et al., 2013). Self-report has some biases; for example patients may not be honest about their compliance, as they may not want to disappoint the clinician. Additionally, if the patients are not tracking their exercises, they may be inaccurate and may over or under estimate the amount of exercises they are doing during the day.

Two articles (Duarte et al., 2013; Krisciunas and colleagues, 2017) had their participants record their exercises on a detailed therapy checklist/form. Therefore, while their data was still based on self-report, it was a more accurate measure of the participants' behavior and the researchers had more detail of the amount of exercise the participants were completing each week. While this method of compliance tracking may be more reliable, it has not been implemented into most clinical setting, as patients may find it tedious and forget to track their exercises.

Shinn and colleagues (2013) used another method to measure compliance. During the clinical visits with the SLP, the clinician observed the clients performing the prescribe exercises and judge their performance as competent or not competent which was classified as adherent or non-adherent respectively. The researchers described that this was consistent across all clinicians and across each clinical visit. Thus the researchers' measurement of compliance is more reliable across participants, however competencies in the exercise is obscure and may not be an entirely valid measure of compliance.

With the increase in technology an exercise compliance app is feasible, reminding the patients everyday to not only do their exercise but record the amount of exercise that they did. This app combined with Shinn and colleagues (2013) method of judging competency in the exercises to measure compliance would be an ideal procedure to gather compliance data.

Currently, clinicians and researcher do not know the amount of exercise needed in order to see benefits in HNC patients. Ideally, if SLPs had the means and support to measure compliance in a reliable and standard way, the quality of compliance data would improve. This would allow for a prospective in-depth analysis of dosage/outcome relationship and give clinicians insight into how much exercise should be prescribed.

The compliance rate across the studies and the current retrospective review ranged from 45% to 66%, and was approximately 68% in the Canadian critical review. Overall, this is higher than the average patient compliance Krekeler and colleagues (2012) reported, but still suggest that complying with swallowing exercise is difficult for patients. Barriers and facilitators to adherence have been explored (Govender et al., 2017a; Govender et al., 2017b; Shinn et al., 2013; Wall et al., 2017); pain and discomfort and not understanding the importance of the exercise were major barriers. How to facilitate better compliance should continue to be explored, and perhaps the previously described app used to track compliance may make patients more compliant, however this needs to be investigated.

Clinical Implications

The critical review suggested that compliance with exercise positively impacts swallowing outcomes. This was not consistent with the Canadian retrospective review; however, this may be due to small sample size and inconsistent compliance tracking. Clinicians should continue to encourage and facilitate HNC patients to perform the exercises before and during treatment. A standard method of measuring compliance and support for clinicians to track compliance is needed to gain insight into an effective dosage of exercise. How compliance with exercises affects swallowing outcomes needs to be examined prospectively.

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Appendix One

Search Terms

PubMed (Yielded 22 papers):
((((("deglutition disorders"[MeSH Terms] OR ("deglutition"[All Fields] AND "disorders"[All Fields]) OR "deglutition disorders"[All Fields] OR "dysphagia"[All Fields]) AND ("exercise"[MeSH Terms] OR "exercise"[All Fields] OR "exercises"[All Fields])) AND ("patient compliance"[MeSH Terms] OR ("patient"[All Fields] AND "compliance"[All Fields]) OR "patient compliance"[All Fields] OR "compliance"[All Fields] OR "adherence"[All Fields] OR “treatment adherence and compliance” OR "compliance"[MeSH Terms] OR "Oropharyngeal Neoplasms/radiotherapy"[MAJR])) AND ("head and neck neoplasms"[MeSH Terms] OR ("head"[All Fields] AND "neck"[All Fields] AND "neoplasms"[All Fields]) OR "head and neck neoplasms"[All Fields] OR "oropharyngeal cancer"[All Fields] OR ("head"[All Fields] AND "neck"[All Fields] AND "cancer"[All Fields]) OR "head and neck cancer"[All Fields])) AND (outcome[All Fields] OR outcomes[All Fields] OR Outcome, Treatment[MeSH Terms])

Scopus (Yielded 18 papers – 17 previously found, 1 new):
(TITLE-ABS-KEY ("deglutition disorders") OR TITLE-ABS-KEY (dysphagia) AND TITLE-ABS-KEY (exercise) AND TITLE-ABS-KEY ("patient compliance") AND TITLE-ABS-KEY ("head and neck cancer") OR TITLE-ABS-KEY ("head and neck neoplasms") OR TITLE-ABS-KEY (head) AND TITLE-ABS-KEY (neck) AND TITLE-ABS-KEY (cancer) AND TITLE-ABS-KEY (outcome))

PsychInfo (Yielded 2 papers, one that was not accessible and one unpublished thesis):
("deglutition disorders" OR "dysphagia") AND ("exercise" OR "exercises") AND ("patient compliance" OR "compliance" OR "adherence" OR "treatment adherence and compliance") AND ("head and neck neoplasms" OR "oropharyngeal cancer" OR "head and neck cancer")

Appendix Two

Table 1. Patient and Compliance Characteristics and Outcomes

Characteristic	*Overall (38)*	*Compliance (n)*			*High Vs. Low and No p value*[a]
		High Compliance (26)	*Low Compliance (6)*	*No Compliance (6)*	
Age, mean (range)	59.97 (45-77)	59.35 (49-77)	62.67 (59-66)	60.00 (45-66)	.218
Sex					
Male	34	22	6	6	.151
Female	4	4	0	0	
Site					
Oropharynx	30	20	5	5	.652
Nasopharynx Or Layrnx	8	6	1	1	
P16					
Positive	19	12	3	4	
Negative	6	6	0	0	.192
Not Known	13	8	3	2	
PSS Diet 3 Months (SD)		57.20 (7.87)	58.33 (17.22)	57.00 (33.20)	.919
FOIS Diet 3 Months (SD)		5.28 (.84)	4.67 (2.42)	5.40 (.89)	.911
MDADI 3 Months (SD)		75.78 (14.61)	82.80 (15.12)	69.45 (16.33)	.767
MDADI 12 Months (SD)		80.17 (13.09)	80.79 (16.63)	75.48 (22.41)	.902

For P16 Negative and Not Known were grouped together for analysis.

[a] Pearson Chi-Square (2-tailed) for categorical variables; Independent-Samples Mann-Whitney U Test for continuous variables