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Research Article

Pressure Equalization Tube Surgery Postponement due to COVID-19: Impact on Cost and Quality of Life

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ABSTRACT

Objectives: To estimate the impact on healthcare costs and patient quality of life secondary to postponement of Pressure Equalization Tube (PET) surgery for Otitis Media (OM) in children due to the COVID-19 pandemic.

Methods: A prospective cohort study was performed following patients whose PET surgery was postponed to a later date due to COVID-19. Patients were followed from the originally scheduled surgery date until PET placement or definitive cancelation (intervention), then afterwards for an equivalent time. Four weeks after the original surgery date and every four weeks thereafter, quality of life was measured using the OM-6 and patients' healthcare utilization were assessed. True healthcare costs and predicted healthcare costs had the pandemic not occurred were compared. OM-6 scores were compared within and between groups during the pre-intervention and post-intervention time periods.

Results: Nineteen patients were included in statistical analysis. Thirteen underwent PET surgery; six patients' surgeries were canceled during the study. The true healthcare cost was $10,750.09 while the predicted healthcare cost was $13,879.52. The OM-6 paired mean decreases in the postponed surgery group and canceled surgery group were significant at 1.3 and 0.78, respectively; however, the mean change between the two groups was not. There was no significant difference in OM-6 score between the surgery and canceled surgery groups before intervention, 2.5 and 2.0, respectively.

Conclusion: Postponement of PET placement due to COVID-19 decreased both total healthcare costs and patients' quality of life.

Keywords: COVID-19; Pressure equalization tubes; Cost; Quality of life; Postponement

INTRODUCTION

The disruption created by the COVID-19 pandemic has placed unprecedented strain on the healthcare system. It is estimated that over 28 million elective operations were canceled or postponed worldwide between March 2020 to May 2020 in order to promote social distancing and conserve resources.[1] Among patients whose procedures were canceled were children scheduled for Pressure Equalization Tube (PET) placement secondary to Otitis Media (OM), including both Otitis Media with Effusion (OME) and recurrent acute otitis media (AOM). PET placement is the most common pediatric ambulatory surgery in the United States with nearly 1 in 15 children having a set placed by age three. Opinions regarding the precise timing and indications of PET placement versus medical management have evolved over time, but surgery remains a popular treatment paradigm as it rapidly treats and decreases future incidence of OM when compared to active monitoring.[2] There is little risk of long-term adverse outcomes to patients when surgical treatment is delayed; however, the risk of continued OME or subsequent episodes of AOM is high, potentially adversely affecting the quality of life of both the patients and their families.

It is estimated that pediatric OM accounts for $2.88 billion in healthcare costs.[3] Delay in surgical treatment may add to costs by increasing medication use and visits to healthcare providers. Postponement or cancelation of elective surgery due to the COVID-19 pandemic creates a unique opportunity to study these cost implications. By prospectively following a cohort of patients whose PET surgery was postponed, we aimed to determine if postponement increased the overall healthcare costs generated by these patients and its impact on their quality of life.

MATERIALS AND METHODS

Prior to beginning the study, institutional review board approval was obtained from Washington University Medical Center Human Research Protection Office along with a waiver of written consent and waiver of HIPAA authorization. We performed a single-center, prospective, cohort study following patients whose PET surgery was postponed due to the COVID-19 pandemic. Patients were identified for surgery using clinical practice guidelines outlined by the American Academy of Otolaryngology – Head and Neck Surgery.[4] Patients older than 6 months originally scheduled for surgery between March 2020 and May 2020 at St. Louis Children's Hospital and the Children's Specialty Care Center (ambulatory surgical center) were included. Patients scheduled for PET placement in association with other surgical procedures, patients under 6 months of age, and cases without informed consent were excluded. Patients were recruited via telephone. During the initial call, the purpose and design of the study was explained and verbal consent to participate was obtained. Ongoing consent was implied through participation in subsequent calls.

Outcomes were gathered via questionnaires completed by telephone to facilitate social distancing. The first questionnaire was completed four weeks after the original date of surgery. Questionnaires were repeated every four weeks until surgery was completed and on the surgical date. For those who did not undergo surgery, questionnaires were performed on the same schedule until the date of definitive cancelation. Cancelation occurred secondary to a lack of OM signs and symptoms, which was determined either by the patient's caregiver at home or by the patient's surgeon in a clinical setting. Surgery or cancelation were considered a patient's intervention. After surgery was completed or canceled, the questionnaire was administered every four

weeks for a period equal to the duration of the postponement. Questionnaires completed within five days of official four-week time points were considered valid. One researcher delivered all questionnaires, and one caregiver was surveyed for each patient.

During each administered questionnaire, caregivers were asked to report any OM related healthcare utilization over the preceding four weeks including visits to any healthcare providers and use of any prescription medications to treat OM. Healthcare related expenditures were calculated according to the recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine.[5] The most current data available from the Centers for Medicare and Medicaid Services (CMS) were used to estimate costs accurately. The cost of visits to healthcare providers was estimated by using the CMS Level 3, Non-Facility Price pay schedule for outpatient office visits. Medicare Part D data from 2018 was used to estimate medication costs. Because numerous individual Medicare Part D plans exist, the authors used Average Spending Per Claim data and treated each course of medication use reported as one claim. Medicare CPT codes from 2019 for "incision of eardrum with insertion of eardrum tube under general anesthesia" in both ambulatory surgical centers and hospital outpatient departments were used to estimate the cost of PET placement. Non-healthcare related costs were not included as our emphasis is to determine total healthcare cost implications specifically.

The true total healthcare cost was calculated and compared to the predicted cost for the cohort had surgery had been completed as scheduled. Predicted costs included a standard post-operative care regimen consisting of one round of ofloxacin ear drops starting immediately after surgery and one post-operative visit.

Quality of life was measured using caregiver completion of the OM-6 questionnaire, a validated, condition-specific survey for pediatric OM (Figure 1). It assesses impact on quality of life due to physical suffering, healing loss, speech impairment, emotional distress, activity limitation, and caregiver concerns. The OM-6 has demonstrated good test and retest reliability and is minimally influenced by symptoms due to other conditions.[6,7] OM-6 scores were compared between groups of patients who ultimately received and did not receive surgery as well as before and after intervention for each patient.

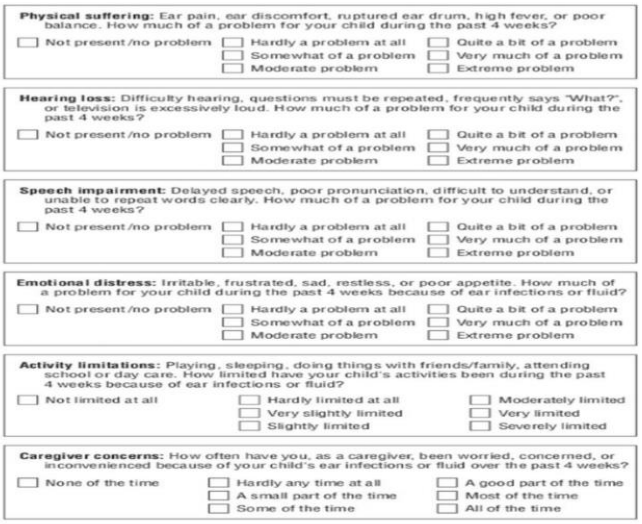

Figure 1: The OM-6 Questionnaire

Statistical Analysis

The true and predicted total healthcare cost and mean cost per patient were calculated and analyzed. Average OM-6 scores before and after intervention were calculated for each patient. Significance of OM-6 score changes within and between groups was evaluated using paired sample t-tests and independent t-tests. Cohen's *d* effect sizes are reported. Confidence intervals (CI) were calculated using 95% confidence. Non-parametric data comparisons between groups were performed via Mann-Whitney U testing. Statistical analyses were performed using SPSS software ver. 27.0 (IBM, Armonk, NY, USA).

RESULTS

Thirty-seven patients had their PET placement surgery postponed. One was excluded prior to recruitment due to being scheduled for multiple procedures in conjunction with PET placement. Of the remaining 36 patients, seven could not be contacted for initial recruitment and one opted out. Nine additional patients gave consent to participate but were eventually lost to follow-up. A medical record search 12 weeks after the last questionnaire was delivered determined that 6/9 (67%) patients lost to follow up eventually had surgery. Regarding the 19 remaining patients in the study, 13/19 (68%) were male, 6/19 (32%) were female, 17 (90%) were white non-Hispanic, one (5.3%) was Asian, and one (5.3%) was African American. The average participant's age was 29.3 months, ranging from 9-79 months (Table 1). On average, 15 days elapsed between the date of original surgery scheduling and the date of surgery postponement.

Thirteen (68%) patients eventually had surgery while six ultimately had their procedures canceled due to clinical improvement. The average time between the original surgery date and actual surgery date or definitive cancelation was 40 days and 45 days, respectively. Twelve (63%) patients consumed healthcare resources other than surgery during the study period including PCP visits (15), ER visits (2), otolaryngologist visits (1), courses of amoxicillin-clavulanate (3), courses of cefdinir (2), non-perioperative courses of ofloxacin drops (7), perioperative courses of ofloxacin drops (13), and courses of ciprofloxacin-dexamethasone drops (1). The true healthcare costs totaled $10,750.09, averaging $565.79 per patient (Table 3). The predicted total healthcare cost had the COVID-19 pandemic not occurred was $13,879.52, averaging $730.50 per patient. Predicted costs included PET placement, one course of ofloxacin drop, and one post-op visit for all 19 patients.

OM-6 mean averages were compared to assess for statistical differences in quality of life in three ways. First, the average OM-6 scores decreased for all patients before and after intervention. In the postponed surgery group, the mean OM-6 score before and after intervention decreased from 2.5 to 1.2. The paired mean change (1.3) was statistically significant (p=0.001; CI=0.68-2.0), and the effect size was 1.2. In the canceled surgery group, the mean OM-6 score before and after intervention decreased from 2.0 to 1.2. The paired mean change (0.78) was statistically significant (p=0.026; CI=0.14-1.4), and the effect size was 1.3 (Table 2). Next, the postponed and canceled groups' mean changes were compared to each other. There was no statistically significant difference between the mean changes (p=0.269; CI=-1.6-0.46), and the effect size was -0.58. Lastly, the postponed and canceled groups were compared prior to their respective intervention to assess for differences at the beginning of the study using Mann-Whitney U. There was no statistically significant difference (p=0.639 CI=-1.5-0.50) between the postponed group (2.5) and cancelation group (2.0); the effect size was -0.12.

Table 1: Baseline Characteristics of Nineteen Patients in Cohort.

Race	**White Non-Hispanic**	17/19 (90%)
	Asian	1/19 (5.3%)
	African America:	1/19 (5.3%)
Sex	**Male**	13/19 (68%)
	Female	6/19 (32%)
Age	**Mean (mo)**	29.3
	Range (mo)	9-79
Surgery Occurred	**Yes**	13/19 (68%)
	No	6/19 (32%)

Table 2: OM-6 Comparison within Postponed Surgery and Canceled Surgery Groups.

Group	Mean (SD) OM-6 Pre-Intervention	Mean (SD) OM-6 Post-Intervention	Mean Difference (SD) Between Pre and Post	Confidence Interval (CI)	Effect Size (Cohen *d*)
Postponed Surgery	2.5 (1.1)†	1.2 (0.15)	1.3 (1.1)	0.68-2.0	1.2
Canceled Surgery	2.0 (0.60) †	1.2 (0.24)	0.78 (0.61)	0.14-1.4	1.3

†No statistically significant difference between Postponed Surgery and Canceled Surgery groups prior to their respective intervention via Mann-Whitney U; p=0.639; CI=-1.5 to 0.50; effect size=-0.12.

Table 3: Healthcare Costs Associated with COVID-19 Postponements and Cancelations.

Expense	Number Consumed	Cost per Unit (USD)	Total Cost (USD)
Primary Care Provider and ENT Visit	16	76.15	1,218.40
Emergency Room Visit	2	52.33	104.66
Amoxicillin-Clavulanate (courses)	3	12.66	37.98
Cefdinir (courses)	2	24.32	48.64
Ofloxacin Otic Drops (non-perioperative time)	7	27.93	195.51
Ofloxacin (perioperative courses)	13	27.93	363.09
Ciprofloxacin-Dexamethasone Otic Drops (courses)	1	227.81	227.81
Incision of Eardrum with Insertion of Eardrum Tube Under General Anesthesia at Ambulatory Surgical Center	11	558	6,138
Incision of Eardrum with Insertion of Eardrum Tube Under General Anesthesia at Hospital	2	1,208	2,416
			Grand Total: $10,750.09

DISCUSSION

Initially we postulated that delaying surgery might decrease quality of life and increase use of antibiotics and visits to healthcare providers, increasing healthcare costs. The cohort's true total healthcare cost was $10,750.09, $3,129.43 less than the predicted costs had surgery been completed as scheduled. These data demonstrate that postponement or cancelation of surgery in this cohort was not associated with higher total

healthcare costs. The difference in cost is largely due to the six patients who ultimately did not receive surgery, suggesting that the increased healthcare utilization generated by additional episodes of AOM was more than balanced by the savings generated by surgery cancelation.

Because PET placement rapidly and effectively treats OM, surgical delay caused decreased quality of life in the cohort. Both the postponed and canceled surgery groups' quality of life significantly improved after intervention and by a similar extent. Notably the patients who received PET had statistically similar OM-6 scores compared to those who did not have surgery during their pre-intervention time periods. The observed lack of quality of life variation but potential cost savings in this cohort further highlights the challenges clinicians face when choosing patients for PET placement.

Although PET placement is performed on about 1 million children in the United States each year, nearly all are considered elective, and antibiotic treatment alone can frequently be used to treat AOM.[8] Controversy over PET indications persists in the pediatric otolaryngology community worldwide especially when clinicians are faced with more nuanced patient situations and pathologies.[9] Placement of PET does incur more upfront costs to the healthcare system but comes with the benefit of decreased future incidence of OM, thereby increasing and maintaining quality of life and limiting the need for extra healthcare utilization. Several groups have performed cost-utility analyses attempting to address the balance of cost versus quality of life improvement. Conclusions range from recommending PET in very select patients to recommending it as optimal treatment associated with high quality of life and low long-term cost.[10,11] The wide range of recommendations suggests that definitive cost-utility conclusions have yet to be determined.

The time period of study from spring to early summer should be noted. It is well known that the incidence of acute OM in children decreases from late spring to early fall in North America.[12,13] Additionally, at the time of this review there was a decrease in the social interactions among children through daycare and school related activities due to COVID-19 related shutdowns. These factors likely skew quality of life to appear higher and healthcare cost to appear lower than one would observe at other times of year. Had this cohort been studied when OM's natural incidence is high and when children are regularly attending school and daycare, the rate and severity of OM would likely be increased, leading to fewer canceled surgeries, higher antibiotic use, and decreased quality of life.

Limitations

This study is limited by the restricted sample size. A relatively small cohort was identified, and during the postponement, few new patients were seen in outpatient clinics. No new patients could be added to the study prior to elective surgeries being phased back into daily workflow. Caregiver and healthcare provider behaviors were almost certainly influenced by concerns for exposure to COVID-19. As a result, conclusions may not be directly applicable to other circumstances where placement of PET may be delayed. Furthermore, the follow up period was too short to determine if resumption of school and daycare affected caregiver's motivation to pursue PET placement. Lastly, the calculation of healthcare costs is inexact and an area of ongoing debate. Conclusions drawn regarding cost may not be applicable across all healthcare environments.

CONCLUSION

The COVID-19 pandemic caused an unprecedented number of canceled or postponed elective surgeries, affecting cohorts of patients worldwide. These unique, temporary circumstances allowed us to study the impact of postponement on total healthcare costs and quality of life in pediatric patients with OM, which would not be possible during standard clinical operations. Despite initial predictions of both a total increase in healthcare cost and a decrease in quality of life, our data demonstrates that while postponement did adversely affect quality of life, OM related healthcare costs decreased in this cohort as a result of the COVID-19 pandemic. While the pediatric OM population is relatively small, some of the conclusions drawn in this review may be applicable to the broader ambulatory surgery population and be useful in planning for possible surges in COVID-19 or other future pandemics.

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