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ORIGINAL RESEARCH PEDIATRIC ANESTHESIA

Development and implementation of the new clinical research program in a rural hospital for children undergoing myringotomies or tonsillectomies and adenoidectomies

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ABSTRACT

Background & Objective: Pediatric sub-specialty procedures are usually performed in large hospitals by specialists. We aimed to develop a protocol in pediatric patients undergoing bilateral myringotomies (BMT) or tonsillectomies and/or adenoidectomies (T&A) in a rural community hospital.

Methodology: An IRB-approved, prospective study was performed at Lexington Medical Center to examine the safety (S), emergence (E), and efficacy (E) (SEE) of an anesthetic protocol in patients under 7 y of age undergoing BMT or T&A. A non-specialist anesthesiology-based team performed the protocol related to SEE.

Results: Out of 60 patients enrolled in the study, 4 (6.6%) desaturated (lowest SpO_2 87%), and 6 (10%) had poor quality of emergence from anesthesia. The mean times for induction, emergence, and surgery for BMT were 4.8 ± 1.3, 4.2 ± 2.2, and 3.9 ± 1.0 min respectively. The mean times for induction-intubation, emergence-extubation, and surgery for T&A were 9.0 ± 2.9, 12.1 ± 6.8, and 14.6 ± 5.8 min respectively.

Conclusion: The development of a clinical research program and study protocol was achieved for pediatric ENT procedures at a rural hospital. We found that Lexington Medical Center had a low incidence of desaturation, good quality of emergence from anesthesia, and efficacy.

Key words: BMT: bilateral myringotomies; Desaturation; Emergence; Protocol; Pediatric;

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1. INTRODUCTION

Pediatric otolaryngology (ENT) procedures, especially bilateral myringotomies with tube placement (BMT) and tonsillectomies and adenoidectomies (T&A), are frequently performed at private academic children's hospitals in large cities and suburban areas.[1] In contrast, rural facilities may lack pediatric surgical sub-specialties, therefore general anesthesiologists and otorhinolaryngologists have to perform these procedures.[2,3] Financial stress in rural areas has allowed large academic centers and hospital systems to expand into rural areas, thereby offering the potential opportunity for patients to be enrolled in clinical research studies.[4,5] However, the infrastructure for Institutional Review Board (IRB) approved studies usually lacks in these rural hospitals.[6]

Rural hospitals may need assistance in developing clinical research programs. The specific needs of their patients may differ from those in urban areas. Previous clinical research protocols have been developed in rural areas for adult patients undergoing total joint arthroplasty and endoscopic procedures but not for children.[7,8]

We developed a clinical research program consisting of a (1) quality assessment (QA), (2) quality improvement (QI), and (3) an IRB approved clinical study for children undergoing ENT surgery in a rural hospital. The goal of the program was to develop and evaluate an anesthesia protocol with safety (S), quality emergence (E) and efficiency (E) or 'SEE'. Safety was measured as the incidence of perioperative desaturations, quality of emergence from anesthesia was measured using the pediatric anesthesia emergence delirium (PAED) scale, and efficiency was measured as times to complete induction (TI) and emergence (TE) for BMT and induction-intubation (TII), emergence-extubation (TEE) for T&A, and surgical times (ST).

We present our experience and challenges with the development and implementation of a clinical research program in a rural hospital.

2. METHODOLOGY

An IRB-approved, single-arm prospective observational study was performed at Lexington Medical Center (LMC) in Lexington, North Carolina part of the Wake Forest Baptist Health System of Winston-Salem, North Carolina. Children under seven years of age, who underwent BMT or T&A, were recruited. Written consent was obtained from the parents/legal guardians.

We conducted a three-part QA, QI program and an IRB study (Figure 1).

2.1. Goals

The goal of the initial QA portion (Part 1) was to identify areas of possible improvement regarding safety in airway management by defining measurements of outcome. We used incidence of perioperative desaturations and degrees of hypoventilation observed from the different anesthetic techniques to evaluate areas of further investigation and improvement.

The goal of the QI portion (Part 2) was to develop a clinical protocol which included additional measures such as the quality of emergence from anesthesia and the efficiency regarding the times for anesthetic induction, surgical time and emergence from anesthesia for the respective procedures.

After the establishment and implementation of the QA and QI program, the development of the third part was an IRB study protocol (Part 3) for the anesthetic and surgical management of patients with emphasis on the challenges pertinent to the rural care setting.

The protocols for BMT and the T&A procedures were developed by specialists in pediatric anesthesiology so that a group of general/non-specialist anesthesiologists and nurse anesthetists would be able to improve the outcomes of these procedures. The surgery was performed by one board certified ENT surgeon.

Our IRB study aimed to develop a simple anesthetic protocol described as SEE, that would evaluate three dimensions of patient care quality: to evaluate an anesthetic protocol for safety (S) of airway management (via incidence of perioperative desaturations), quality of emergence (E) from anesthesia, and efficiency (E) of the procedure.

2.2 Data Collection

Data was collected by research assistants trained in the clinical data collection, protocols and conceptual knowledge of relevant patient care procedures. They did not participate in patient care, and therefore were independent of clinical care but were present during the entire time from preoperative to discharge from the post anesthesia care unit (PACU). In this way, data was recorded in real-time for the observational study (Appendix A and B). Data included demographics, comorbidities and complications or issues related to SEE.

Safety (S) was measured as issues related to airway management including the incidence of desaturations and hypoventilation from induction of anesthesia to

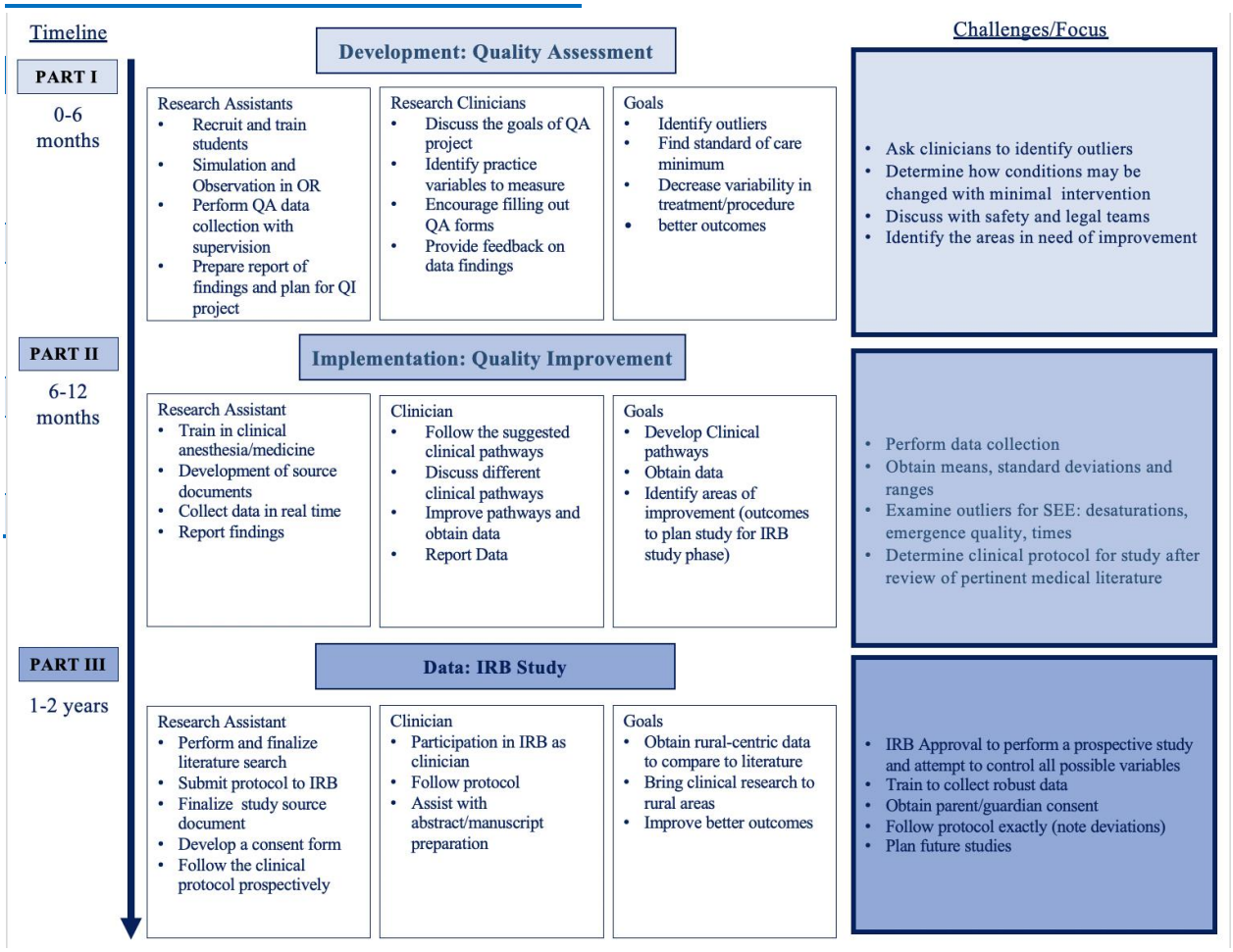

Figure 1: Flowchart of development, implementation, and completion of QA, QI, and IRB study.

discharge home. A desaturation was defined as SpO_2 < 95%. The Pediatric Anesthesia Emergence Delirium (PAED) scale was used to measure the quality of emergence from anesthesia (E) in PACU and prior to discharge home [9]. A PAED score of > 10 was defined as poor emergence. Efficiency (E) was determined by the time spent in induction/intubation, surgery, and emergence/extubation as related to total in-room time.

2.3 Protocol

An anesthesiology-based team, comprised of general anesthesiologists and certified registered nurse anesthetists (at times with student nurse anesthetists), performed the respective protocols shown in Figure 2 (BMT) and Figure 3 (T&A). The area deprivation index was collected based on patients' 9-digit zip code using data provided by the Neighborhood Atlas.[10]

3. RESULTS

Our study included 60 patients as shown in Table 1. Two patients were excluded due to missing data.

Table 1: Patient demographics

Parameter	BMT (n = 44)	T&A (n = 16)
Age (months)	35.3 ± 21.5 (7−81)	51.3 ± 19.2 (20−74)
Weight (kg)	16.3 ± 8.0 (8.2−43.7)	19.4 ± 6.0 (10.2−35.4)
ASA		
I	30 (68.2)	7 (43.8)
II	14 (31.8)	8 (50.0)
III	0 (0)	1 (6.3)
Gender		
Male	27 (61.4)	9 (56.3)
Female	17 (38.6)	7 (43.8)

Data presented as mean ± SD (Range) or n (%)

3.1. Safety (S): oxygenation and ventilation issues

Four (6.6%) patients, all undergoing T&A, desaturated

with the lowest SpO_2 being 87%. Of the four

desaturations, one patient had obstructive sleep apnea (OSA) and another upper respiratory tract infection (URI). No patient experienced desaturations during induction; three patients experienced mild desaturations during maintenance (= 90%, 91%, and 95%, respectively). Two patients with the lowest desaturations also required administration of albuterol during maintenance.

Problems with ventilation occurred during maintenance and emergence-extubation. A patient undergoing an adenoidectomy with URI had an $EtCO_2$ of 87 mmHg on emergence. Lastly, two patients had $EtCO_2$ levels of 60 and 61 mmHg during maintenance.

3.2. Quality of Emergence from Anesthesia (E)

See Figure 4 for PAED scores in the PACU and Second Stage.

In the PACU, 4 (7.8%) patients exhibited poor quality of emergence defined as a PAED score >10. In the second stage, only 2 (3.8%) patients exhibited poor emergence quality (Figure 4). The patients with the highest PAED scores of 13 and 15 did not have any other complications. One patient with a PAED score of 11 desaturated to 95% during maintenance. The patients with the lowest PAED scores (0–3) in PACU and second stage were 71.8% and 92.3%, respectively for BMT and for 50% and 78.6%, respectively for T&A.

3.3. Efficiency (E)

The total time spent in the operating room as well as the specific times for TI, TII, TE, TEE, ST, PACU, and second stage for BMT and T&A respectively are shown in Table 2.

3.4. Area Deprivation Index (ADI)

The mean ADI of our patients was 64.9 ±13.1 nationally and 6.1 ± 1.8 state-wide.

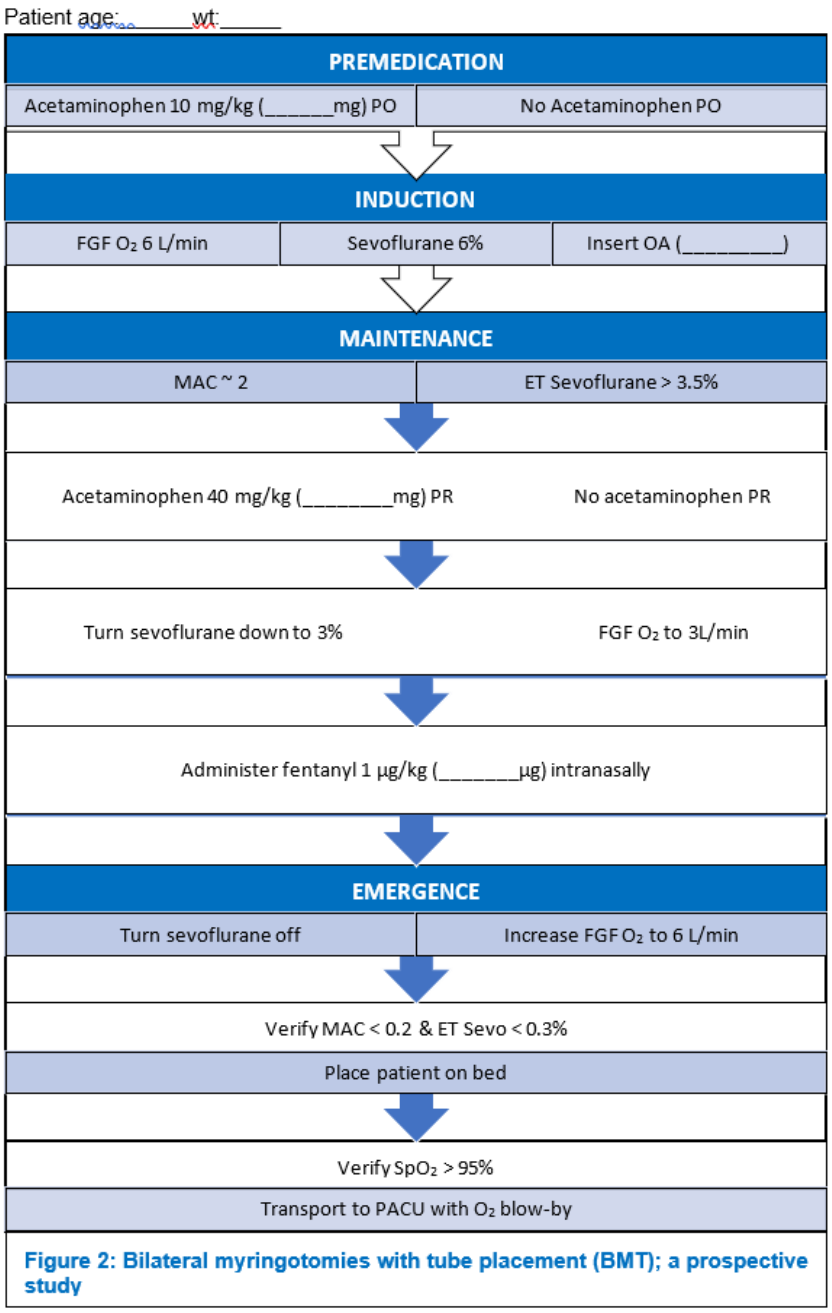

Figure 2: Bilateral myringotomies with tube placement (BMT); a prospective study

4. DISCUSSION

We successfully developed a rural-focused clinical research program that consisted of a three-part QA, QI, and an IRB approved study protocol for non-pediatric specialized anesthesiologists and nurse anesthetists in children undergoing BMT and T&A. We found a low incidence of desaturations, enhanced quality of emergence from anesthesia reflected by low PAED scores, and efficiency of care as reflected by the times of the phases of care.

4.1 Quality of Airway Management

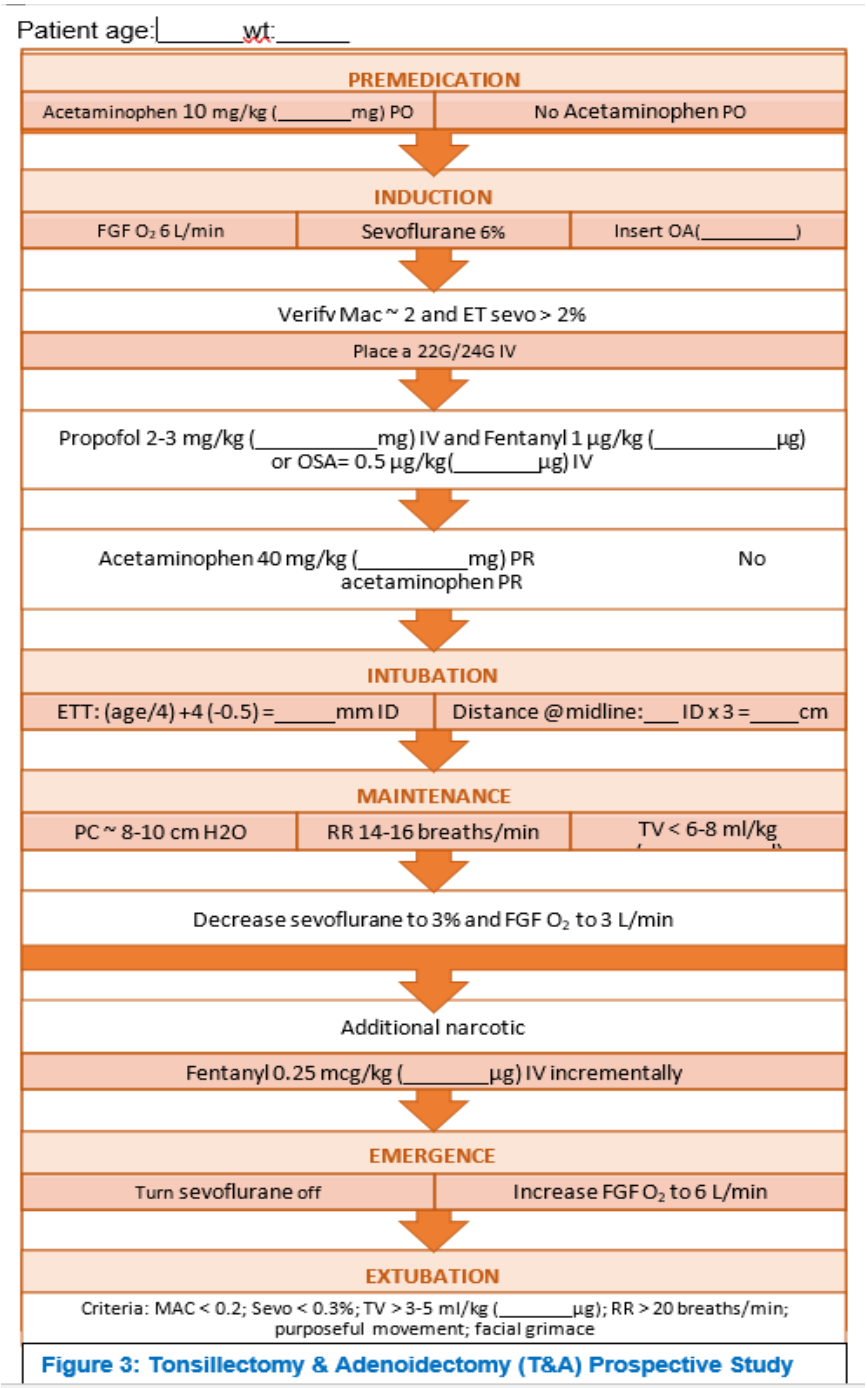

Figure 3: Tonsillectomy & Adenoidectomy (T&A) Prospective Study

Our incidence of desaturation, 6.6%, was less than the study by Lemoto et al. of 11% desaturations (SpO_2 < 92%). Their study included a greater number of children but was retrospective in nature.[11] Another retrospective study by Kieran et al. examined post-tonsillectomy risk factors and found an incidence of desaturation (SpO2 < 90%) of 7.2%. Their study was conducted at a large tertiary care center in patients with higher ASA scores.[12] Similarly, Unger-Sternberg et al. found an incidence of 10% desaturations in a prospective study of perioperative adverse respiratory events based on a questionnaire.[13]

A study by Mamie et al. found the incidence of adverse respiratory effects was influenced by the age of the child and the anesthetic care provided.[14] Regarding ventilation in our study, we placed an oral airway and applied low levels of CPAP< 10 cm H_2O in a large number of patients. Jacob et al. quantified induction difficulty on scale of 1-6, however, their positive air pressures were not measured in cm H_2O.[15]

4.2 Quality of Emergence

In our study, the quality of emergence from anesthesia scored by PAED found high scores of 8% and 2% in the PACU and second stage, respectively. Our findings are similar in comparison to others regarding emergence delirium as Bryan et al. found an incidence of 7% in patients undergoing non-painful MRI brain scans.[16] In comparison, Rampersad et al. found an incidence of emergence agitation between 13 to 18% in patients who underwent BMT.[17] Isaiah and Pereria found emergence agitation improved when a protocol was followed in patients with OSA who underwent T&A.[18]

4.3 Efficiency of Care

Regarding efficiency of care, we found that the times of anesthetic induction and emergence (intubation/extubation for T&A) were comparable to other studies.[18,19] Dewyer et al. defined Anesthesia Controlled Time (ACT) as the sum of TII and TEE.[19] Our times for T&A (TII and TEE or (ACT), and ST) were better than that of the pediatric and general anesthesiologists from Dewyer et al.'s study demonstrating that general anesthesiologists following a protocol can achieve efficiency.

4.4 Challenges in Establishing IRB Studies in Rural Care

Our study in a rural hospital obtained comparable

Table 2: Total times during phases of care; [mean ± SD (range)]

Specific time (min)	BMT (n = 44)	T/A (n = 16)
Total Time in Operating Room	15.3 ± 3.2 (10−23)	43.3 ± 12.4 (25−66)
Time in Induction−Intubation*	4.8 ± 1.3 (3−8)	9.0 ± 2.9 (5−15)
Surgical Time	3.9 ± 1.0 (2−6)	14.6 ± 5.8 (8−28)
Time in Emergence-Extubation*	4.3 ± 2.2 (1−10)	12.1 ± 6.8 (6−34)
Time in PACU	12.3 ± 4.3 (7−27)	24.8 ± 6.3 (17−41)
Time in 2nd Stage**	20.2 ± 8.9 (7−48)	44.3 ± 21.2 (18−85)

** Intubation and extubation were only in patients who underwent a tonsillectomy and/or adenoidectomy*

***2nd stage was defined as the time the patient left PACU to the time to discharge home*

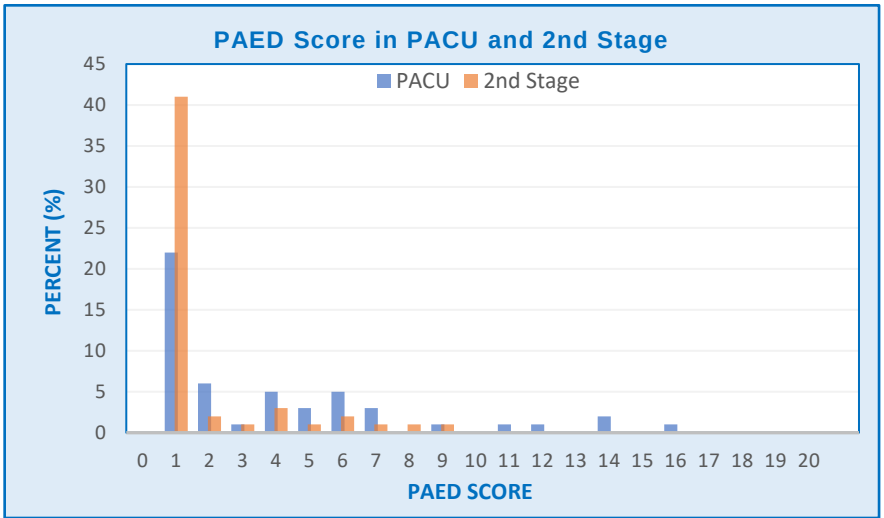

Figure 4: PAED scores in PACU and 2nd Stage

outcome as those obtained at tertiary centers. Although the patients at academic and large hospitals may be more complex, our study was unique to a rural area. We were also able to set up and perform an IRB clinical study in a rural hospital that lacked a protocol. Rather than

extrapolating from studies in the literature performed at large hospitals or academic centers, our goal was to proceed beyond simple QA/QI data and demonstrate how to develop a rural based clinical research program by obtaining our own data and applying it to our patient population.

Among the challenges we experienced firsthand, we found that clinicians initially were not familiar with the academic model related to obligations involved with IRB approved studies, so levels of cooperation varied from the initial development of the QA and QI program. Additionally, some clinicians did not understand their role in the need to train clinical research assistants to the fundamentals of clinical care. Clinicians became aware of the obligations in following good clinical research practices. The clinicians also learned that the requirements imposed on clinician researchers involved in investigator-initiated IRB studies differed significantly than QA/QI projects. Over the course of the project, participation and cooperation with the study increased from that experienced in the early stages of the QA/QI portion.

5. LIMITATIONS

There were several limitations in this study as the protocol was performed at one institution with a small sample size and most patients underwent BMT. It was not randomized, and the endpoints combined different outcomes. The included patients had a deprivation index reflective of an area with higher socio-economic disparity and more disadvantaged children in a rural setting [10]

6. CONCLUSION

As a response to the lack of infrastructure for clinical research and IRB approved studies in rural hospitals, the authors successfully developed a protocol and performed the study. Our goal was to provide a framework for other rural centers to support and conduct their own research and enhance serving their specific patient care requirements. In our center, we found that anesthesiology-based teams consisting of general anesthesiologists and certified registered-nurse anesthetists were able to safely perform BMT and T&A procedures at a small rural hospital. Specialized pediatric anesthetic care may be successfully provided by non-specialists and produce similar outcomes as those at large academic centers. This research may be applied to other surgical procedures and the specific needs of a rural hospital. Pediatric patients and families do not need to travel far to receive specialized care safely. However, the development and implementation portion of the program in rural may pose certain challenges that need to be identified before undertaking IRB studies in rural hospitals.

7. Conflict of Interest:

All authors disclose no conflict of interest for this study.

8. Sponsor or funding source

Wake Forest Baptist Health (Lexington Medical Center)

9. Authors' Contribution

YB, KJ, HH: conduct of study, literature search, statistical analysis, and manuscript editing

KW, JB: literature search, statistical analysis, and manuscript editing

JG, BC: conduct of study and manuscript editing

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Appendix A.1. Lexington Pediatric ENT Study Data Collection Sheet- BMT

Subject Number: _____ Service date: _____ Age: _____ Gender: M F (Please circle)

Weight: _____ Kg. Height: _____ cm. ASA: I II III IV (Please circle)

Diagnosis: _____ Procedure: _____

Significant Comorbidities (Please tick √): ☐OSA ☐parent smoker ☐URI ☐preemie

☐other_____

Clinician: SRNA: _____CRNA: _____ Anesthesiologist: _____

Premedication: Y N (Please circle)

if Y (Please tick √): ☐ Acetaminophen: ____mg ☐ other (sedative, etc.)_____

Baseline room air SpO_2: ____%

Induction

Time in room: _____ Time mask on: _____

☐ Fresh gas flows 6 L/min O_2

☐ Sevoflurane 6%

☐ Oral airway placed

CPAP: _____cm H_2O

☐ Acetaminophen: _____mg PR

Desaturation

Y N (Please circle):

SpO_2: _____%

☐HR < 100 bpm

Maintenance

Time surgery starts: _____

Time surgery ends: _____

☐ Fresh gas flows: ____L/min O_2

☐ Sevoflurane: ____%

☐ Fentanyl: _____ µg intranasal

☐ HR < 100 bpm Y N (Please circle)

SpO_2_____%

Emergence

Time mask off: _____

Time out of room: _____

☐ Fresh Gas Flow: ____L/min O_2

SpO_2_____%

☐ HR < 100 bpm Y N (Please circle)

Figure A.2: Lexington Pediatric ENT Study Data Collection Sheet- T&A

Subject Number: _____Service date: _____ Age: _____ Gender: M F (Please circle)
Weight(kg): _____ Height(cm): _____ ASA: I II III IV (Please circle)
Diagnosis: _____Procedure: _____
Significant Comorbidities: ☐ OSA ☐ parent smoker ☐ URI ☐ Preemie ☐ other_____ (Please tick √)
Clinician: SRNA: _____ CRNA: _____ Anesthesiologist: _____

Premedication: Y N F (Please circle)
if Y: ☐ Acetaminophen: _____ mg ☐ other (sedative, etc.): _____
Baseline room air SpO_2: _____ %

INDUCTION Time in room: _____ Time mask on: _____	☐ Fresh gas flows 6 L/min O_2 ☐ Sevoflurane 6% ☐ Oral Airway Placed ☐ CPAP _____cm H_2O ☐ IV placed _____G ☐ Propofol _____ mg ☐ Fentanyl _____ mcg ☐ Acetaminophen _____mg PR	☐ Desaturation Y N (Please circle) SpO_2: _____% HR < 100 bpm Y N (Please circle) ☐ HR: _____ bpm
INTUBATION Time intubation starts: _____ Time ETT in: _____	Device used: _____ ETT ID: _____ mm Depth inserted: _____cm # Attempts: _____ # Operators: _____ [S C A] Time ETT in: _____ Aids used: _____	☐ Desaturation Y N (Please circle) SpO_2: _____ % ☐ HR < 100 bpm Y N (Please circle)
MAINTENANCE Time surgery starts: _____ Time surgery ends: _____	☐ Fresh gas flow: _____ L/min O_2 ☐ Sevoflurane _____% ☐ Vent PC 8-10 cm H_2O ☐ Vent RR 14-16 breaths/min ☐ Fentanyl _____ mcg ☐ ETCO2 < 55 mm Hg	☐ Desaturation Y N (Please circle) SpO_2: _____ % ☐ HR < 100 bpm Y N (Please circle)
EMERGENCE/EXTUBATION Time ETT out: _____ Time out of room: _____	☐ Fresh gas flow: _____L/min O_2 ☐ Extubation criteria met: Y N (Please circle)	☐ Desaturation Y N (Please circle) SpO_2: _____ % ☐ HR < 100 bpm Y N (Please circle)

Figure A.3: Lexington Pediatric ENT study data collection sheet- BMT & T&A PACU and Second Stage

PACU

Time in: _____ SpO_2: _____% Room Air/Blow-By

PAED Score (5 and 10 min upon awakening):

Eye contact

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

Purposeful actions

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

Aware of surroundings

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

☐ Not at all (4) ☐ Just a little (3) ☐ Quite a bit (2) ☐ Very much (1) ☐ Extremely (0)

Restless

☐ Extremely (4) ☐ Very much (3 ☐ Quite a bit (2) ☐ Just a little (1) ☐ Not at all (0)

☐ Extremely (4) ☐ Very much (3 ☐ Quite a bit (2) ☐ Just a little (1) ☐ Not at all (0)

Inconsolable

☐ Extremely (4) ☐ Very much (3) ☐ Quite a bit (2) ☐ Just a little (1) ☐ Not at all (0)

☐ Extremely (4) ☐ Very much (3) ☐ Quite a bit (2) ☐ Just a little (1) ☐ Not at all (0)

Time out: _____

Second Stage

Time in: _____

Time discharge ready: _____

Time out: _____

Complications

Y N (Please circle)

If Y, phase of care: ☐ Induction ☐ Intubation ☐ Maintenance ☐ Emergence/extubation

☐ PACU ☐ second stage

Non-Airway:

☐ Bradycardia: _____ bpm ☐ Tachycardia: _____bpm ☐ Nausea ☐ Vomiting

☐ other_____

