COVER PAGE

Title: Clinical Use of Baxter Animated Retching Faces (BARF) Scale in Children

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Section Aa: Title & PI

A1. Main Title

CLINICAL USE OF BAXTER ANIMATED RETCHING FACES (BARF) SCALE IN CHILDREN

A2. Principal Investigator

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Section Ab: General Information

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Not set yet

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Pediatric research in the management of nausea has been limited by the absence of a reliable method to quantify the intensity of this subjective symptom. In adults, the visual analog scale (VAS) is an accurate tool, but this has not been shown to be reliable in young children. By default the most common objective outcome measure used in pediatric studies has been the incidence and number of emetic episodes. This measure, however, correlates poorly with the somatic subjective symptom of nausea.

Apfel et al have shown that 30-40% of adult patients undergoing surgery have post discharge nausea and / or vomiting while 12% have vomiting. These data on nausea in adults were based on a visual analog scale for nausea. There are no data on the incidence of postoperative nausea in children since the severity of symptoms are difficult to measure as younger children are known to be unable to use the VAS reliably.

Recently a pictorial scale for measuring nausea, the Baxter Animated Retching Faces (BARF) scale, has been developed and shown to have construct, content and convergent validity as an instrument to measure nausea in children. The clinical usefulness of this scale in determining the incidence of postoperative and post-discharge nausea in children has yet to be determined including the lowest age where it can be used reliably, the score associated with a patient's perception of a need for treatment, the minimum change in the scores of clinical relevance and the test-retest reliability when nausea is rated as not having changed.

Section D: Purpose and Objectives

This study in the pediatric patient population is designed to determine: (1) The incidence of postoperative

nausea as compared to postoperative vomiting in the Post Anesthetic Care Unit (PACU) and on discharge (Post Discharge nausea and Vomiting). (2) The age related differences in the reliability and usefulness of the BARF and VAS scales for measuring nausea. (3) The minimal clinically relevant differences in nausea on the BARF and VAS scales. (4) The BARF and VAS scores associated with a patient's perception of the need for treatment. (5) The test - retest reliability of the VAS and BARF scores when nausea is rated as unchanged.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Child (3-12 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
These are described in section J.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
d) Questionnaire/survey/interview

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The study design is a cross sectional study of patients undergoing surgery. There will be no group assignment, no placebo group and each patient will be his or her own control. Patients will receive standardized care according to the Attending Anesthesiologist?s opinion of the clinical requirements for the specific situation. No changes in clinical practice or care of patients will occur solely for the purpose of the study. All patients will be asked to assess their pain and nausea using the visual analogue scales, the modified faces scale and the BARF scale as described below in the preoperative and postoperative areas. However, the order in which the scales are presented to the patient for assessment will be randomized to reduce the potential for an order effect where the patient choice of a response on one scale may influence the response on other scales. For example, having chosen a response two-thirds of the way up one scale, there will be a tendency to choose a response two-thirds of the way up the next scale.

Inclusion Criteria:

(1) Age > 3 years but below 18 years (2) Elective surgery (3) American Society of Anesthesiologists physical status 1-3 (Free from major concurrent disorders) (4) Free from nausea and / or vomiting in the previous 24 hours (5) Cognitive, visual, hearing and communicative ability to use the VAS as shown by the ability to complete a seriation task in which children pick the biggest of 6 cut out shapes, then the smallest, and the biggest remaining until no shapes remain (Beyer et al: J Pediatr Nurs 1992; 7: 335-46)

Exclusion Criteria:

(1) Developmental delay (2) Blindness (3) Impaired cognitive or communicative abilities including inability to rate the intensity of symptoms and failure to complete the seriation task (4) Surgical procedures which may result in diminished hearing or vision in the immediate postoperative period (5) Nausea and /or vomiting within 24 hours prior to the procedure (6) Inability to understand English, (7) Patient or parental refusal to participate (8) Pregnant females

F2. Procedure

We will first determine if the child will qualify for the study by showing 6 cut out shapes of different sizes and asking the child to first choose the largest size, then the smallest, then the largest remaining size until no more shapes are left. If the child qualifies for the study and if they agree to participate, we will obtain baseline values as described below. Baseline Values: Baseline assessments of nausea before the procedure would be obtained from the awake child using both the visual analogue scale and the BARF scale. The order in which the first scale is presented to the patient for assessment will be randomized to reduce the potential for an order effect. The script for the scales would be standardized in keeping previous studies. For the nausea scales, the script would be: ?Have you thrown up or felt like you were going to throw up before? How did your tummy feel then? We call that feeling of being sick to the stomach as nausea. VAS Scale: On this line the far left indicates ?No nausea? and the far right? Worst nausea ever.? Can you show me on this line how much nausea you have right now? Faces Scale: ?These faces show children who feel no nausea at all, who feel a little bit nauseous, who feel even more nauseous, and these are children who have a lot of nausea.? (Point to the each face at the appropriate time). Which face is more like you right now?? The evaluator will assess if the child has understood the instructions and has the ability to provide a reliable response.

Perioperative Care

After providing baseline values in the preoperative holding area, the patient's anxiety would be assessed using the validated modified Yale Preoperative Anxiety scale (mYPAS) (12), while the child is in the holding area, at the time of separation and when the face mask is applied during induction of anesthesia. The child would receive general anesthesia. The choice of drugs, techniques and perioperative management, including the need (if any) for preoperative medication, will be determined by the Attending Anesthesiologist according to the clinical needs and will not be changed for the purposes of the study. The patient will be monitored in keeping with the standards and policies of the department of Anesthesiology, Texas Children?s Hospital. All Perioperative data will be collected via medical record review. In the Post Anesthetic Care Unit (PACU) patients will receive standard care, including analgesic or antiemetic therapy as prescribed by the Attending Anesthesiologist based on his opinion of the clinical needs of the situation. When awake, the patients will be asked to rate their nausea on both scales (VAS and BARF for nausea). The order of presentation of scales will be the same as in the preoperative area. If a child receives analgesic or antiemetic therapy, he/she will be asked to rate the pain and nausea immediately before receiving the drug and 30-60 minutes after receiving treatment. In summary, patients will rate their nausea using the VAS and BARF scales for nausea at these

time points: (1) before induction of anesthesia, (2) when awake in the PACU, (3) just before, and (4) 30-60 mins after receiving analgesic or antiemetic therapy and (5) just before discharge home. The order of presentation of scales will be randomized but the same for all time points for an individual subject. After the first set of assessments are done in the PACU, patients will also be asked to rate their nausea on a 5 point Likert scale as : (1) Much worse than before, (2) A little worse than before, (3) The same as before (4) A little better than before and (5) Much better than before. They will also be asked if they want any treatment of their nausea. Another set of assessments will be just prior to discharge. All other aspects of patient management will be the standard care given to such children at the Texas Children?s Hospital. Patients will be discharged from the PACU when they have achieved the standard criteria set for discharge at the TCH. At the time of discharge we will give the parents a diary to record the the MAXIMUM nausea on the VAS and BARF scales and mail it back in a stamped envelope. We will phone them about 24 hours after surgery and ask if the child had any nausea, vomiting and what medications were used after going home. We will ask the parent to rate their satisfaction with the control of nausea and with the entire perioperative experience on a 0-10 scale.We will remind them to mail the nausea assessments back and to state which face represented the maximum nausea after discharge.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 387 Worldwide: 387

Please indicate why you chose the sample size proposed:

The study has a number of aims and the power analysis is provided separately for each aim: (1) In order to examine the age related ability to use the BARF scale we will recruit 28 subjects each in the ages of 3, 4, 5, 6 ,7, 8, 9,10,11,12 and >12 years years (28 X 11 = 308). Power analysis was based on an alpha of 0.05, power of 80% and a large effect size (Cohen's d = 0.80) as it was assumed a large difference would be needed for the results to have clinical utility (Pain 2011; 152: 1327-33). This suggested a group size of 24 would be needed. Allowing for a drop out rate of 20% we plan to recruit 28 in each of the 11 groups. (2) Power analysis for minimum clinically relevant difference in BARF scores: A one face difference in the BARF scale is the minimum difference that can be detected. A previous study showed that the mean BARF scores in the postoperative period in children was 1.6 +/- 2.4 (Pediatrics. 2011 Jun;127(6):e1542-9) . In order to detect a 1 face difference with 80% power at the 0.05 level of significance we will need 93 subjects who had a change in their nausea scores. Assuming an incidence of postoperative nausea and vomiting (PONV) of 33% (which is similar to previous data in children), a group size of 93 X3= 279 will be required to obtain 93 subjects with a change in nausea scores. We plan to recruit 387 subjects to allow for a 35% dropout rate.

This sample size will have a >80% power for the other aims of the study (The BARF and VAS scores associated with a patient?s perception of the need for treatment and the test - retest reliability of the VAS and BARF scores when nausea is rated as unchanged.)

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Statistical Analysis: (1) The mean and SD of all scores will be calculated along with their distribution. The incidence of postoperative nausea and postoperative vomiting in the PACU and after discharge (post-discharge nausea) will be calculated. The incidence of severe nausea (score>6 on the BARF scale) and severe vomiting (3 or more episodes over 24 hours) will also be determined. (2) We will record the age of a child and their ability to rate their nausea on the BARF and VAS scales to determine the minimum age where a patient can reliably use the scale. (3) Changes in BARF and VAS nausea scores will be calculated for subjects who report their nausea as a little worse than before or a little better than before, to determine the minimum change in scores of clinical relevance. (4) The BARF score and its relationship to the request for rescue antiemetics will be examined by a Spearman?s rank correlation. (5) The relationship between the first and subsequent BARF and VAS nausea scores in patients who state their nausea is ?the same as before? will be examined by a Spearman?s rank correlation and a Cronbach?s alpha calculation. This will provide the test ? retest reliability.

Section H: Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The risks are limited to possible loss of confidentiality as there are no changes in surgical or anesthetic management of the child other than obtaining data on estimating the degree of nausea. Loss of confidentiality is unlikely in view of standard steps taken to avoid this.

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Subjects will not have any direct immediate benefits from participating in these studies.

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Describe potential benefit(s) to society of the planned work.

Determining the clinical utility of a faces pain scale will facilitate treatment and research into this clinically important realm of suffering for children of all ages. Future patients may benefit from having such a tool as it will permit clinicians to measure the symptom severity and then treat such patients

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

In this study the clinical management of the subject will not be changed in any manner. All decisions will be based on the clinical requirements of the child as judged by the Attending Anesthesiologist and would be the same even if the child did not participate in the study. The minimal risks of loss of confidentiality data is exceeded by the potential benefits to society by demonstrating the clinical utility of a validated tool for measuring nausea in children.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

NA

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

NA

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or

undue influence and consent procedures in detail.

Potental subjects will be identified from the surgery schedule at Texas Children's Hospital that is routinely available to Pediatric Anesthesiology for the purposes of case assignment. Parents of potential subjects will be approached by study staff in the waiting area prior to surgery. After the study is verbally explained, a written consent form will be provided and time given to allow consideration of study enrollment. The consent process will be conducted with emphasis on the voluntary nature of participation and that there is no direct benefit from enrollment. If the parents agree a signed consent will be obtained along with a written assent from the subject when age appropriate.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

NA

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

NA

Specific information concerning alcohol abuse:

NA

Specific information concerning drug abuse:

NA

Specific information concerning sickle cell anemia:

NA

Specific information concerning HIV:

NA

Specific information concerning psychiatry notes:

NA

Demographic information (name, D.O.B., age, gender, race, etc.):
NA

Full Social Security #:
NA

Partial Social Security # (Last four digits):
NA

Billing or financial records:
NA

Photographs, videotapes, and/or audiotapes of you:
NA

Other:
NA

At what institution will the physical research data be kept?
NA

How will such physical research data be secured?
NA

At what institution will the electronic research data be kept?
NA

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
NA

Such electronic research data will be secured via Other:
NA

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
NA

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
NA

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
NA

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

The subject will not be charged for any research related costs. Subject will be charged for drugs and services for patient care that would occur even if the subject did not participate in the study. All research related costs

will be borne by the Department of Anesthesiology, Texas Children's Hospital

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:
0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)
No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug that is not approved by the FDA?
No

Section P: Device Studies

Does this study need an IDE?
No

Regarding your device study, could potential harm to subjects be life-threatening?
No

Regarding your device study, could potential harm to subjects result in permanent impairment of a body function?
No

Regarding your device study, could potential harm to subjects result in permanent damage to a body structure?
No

Section Q. Consent Form(s)

Clinical Utility of the BARF scale

Section R: Advertisements

None