THE EFFECTIVENESS OF MANIPULATION OF PATIENT POSITION
IN CATHETERIZATION OF THE LEFT MAIN STEM BRONCHUS

by

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STATEMENT BY AUTHOR

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APPROVAL BY THESIS DIRECTOR

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May 4, 1973
This study was done as partial requirement for a Master of Science in Medical-Surgical Nursing. In fulfilling this requirement it was necessary that the study be pertinent to nursing and be centered around the purpose of improved patient care.

The author wishes to express special thanks to the physicians and nurses at Arizona Medical Center in the recovery room and Surgical Intensive Care who were so helpful and cooperative during the period of data collection. The Radiology Department was especially helpful in evaluating the chest x-rays. Mr. Wills in Pharmacy and Supply was most cooperative in providing suction catheters for the investigation. Special appreciation to Jane Redman for her ink drawing of the tracheobronchial tree.

Special appreciation is extended to the patients who voluntarily took part in this investigation. Also I would like to acknowledge the assistance of my knowledgeable and able thesis committee, Mrs. Karen Sechrist, Chairman, Dr. Thomas Webster, and Miss Gayle Traver.
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ABSTRACT

Management of secretions is very important in the maintenance of a patent airway. For the patient with an intratracheal tube, tracheobronchial suctioning of both the right and left main stem bronchi is necessary to remove secretions because indwelling intratracheal tubes not only increase the amounts of secretions but reduce the patient's ability to cough and clear his airway.

This study was designed to evaluate the effectiveness of manipulating patients' head position to facilitate selective catheterization of the left main stem bronchus.

The theory that manipulation of patient position could be utilized to significantly improve catheterization of the left main stem bronchus was the basis for the study. Three specific positions for catheterization were used. One position, the control, was with the head midline. The second position was with the head in maximal rotation to the right. The third was with the neck in hyperextension and the head turned maximally to the right. Radiographic determination of catheter position was utilized. The findings were submitted to a chi square analysis using a two by three contingency table and .05 significance level. The data were not statistically significant.
CHAPTER I

INTRODUCTION

The maintenance of a patent airway is an important aspect in the nursing care of many patients, particularly those with tracheostomy, oro-endotracheal, or naso-tracheal tubes. In order to adequately clear secretions from both lungs, it may be necessary to suction both bronchi for which the nurse must be capable of performing tracheobronchial suctioning (Ochsner and Keller 1967).

There is a divergence of opinion regarding the effectiveness of specified head position for tracheobronchial suctioning. The traditional method to enter the left main stem bronchus is to turn the head to the right. To enter the right main stem bronchus the head is turned to the left (Ochsner and Keller 1967). Kirimli, King, and Pfaeffle (1970) indicates that head position does not influence entrance of a suction catheter into the right or left main stem bronchus.

This study concentrates on the use of three head positions in patients who have tracheostomies or are intubated in an attempt to facilitate entrance into the left main stem bronchus with a suction catheter. Catheterization of the right main stem bronchus is accomplished more easily owing to the anatomy of the tracheobronchial tree (see Fig. 1). By devising a method to enter the left main stem bronchus the result should
Fig. 1. Tracheobronchial Tree.
be evacuation of secretions from both lungs and a thorough cleansing of the tracheobronchial tree.

**Statement of the Problem**

Can head position facilitate entrance of a suction catheter into the left main stem bronchus?

**Significance of the Problem**

Suctioning of both bronchi is important in prevention of pulmonary complications resulting from airway obstruction. The significance has been emphasized by James (1967, p. 550), who stated that, the maintenance of a patent airway is the most important of all nursing functions in the immediate post-operative period since all other treatments are useless without oxygenation to maintain life.

**Purpose of the Study**

The investigation of methods to assure adequate airway care, including head positioning for suctioning, is important to the medical and nursing professions. This study focuses upon selective catheterization of the left main stem bronchus to assure clearing of secretions from the left lung.

**Hypotheses to be Tested**

The following hypotheses were tested:

1. A suction catheter will more frequently enter into the right main stem bronchus when the patient's head is in the midline position;

2. A suction catheter will more frequently enter into the left main stem bronchus when the patient's head is in maximal rotation to the right
than when it is in the midline;

(3) A suction catheter will more frequently enter into the left main stem bronchus than into the right main stem bronchus when the patient's neck is hyperextended and his head in maximal rotation to the right than when it is midline or turned to the right.

**Theoretical Framework**

Adequate tracheobronchial suctioning depends upon entering both bronchi. Owing to the anatomy of the tracheobronchial tree, current techniques may be inadequate for left bronchus catheterization.

The anatomy of the trachea is of definite significance when determining the feasibility of manipulating a patient's position to facilitate entrance of a catheter into the desired main stem bronchus (Fraser and Pare 1971). The trachea, a cartilaginous and membranous tube, originating in the neck, extends to the upper edge of the fifth thoracic vertebra at which point a ridge exists that internally separates the openings of the two main stem bronchi. This ridge is called the carina (Gray and Grass 1964).

The right bronchus is wider and shorter than the left one. It leaves the trachea at approximately 25°. In contrast, the left bronchus angles from the trachea at about a 45° angle. Hollinshead (1967) believes, that due to its greater size and because it more nearly continues the vertical direction of the trachea, the right bronchus is much more likely than the left to receive a foreign body. The anatomy of the tracheobronchial tree contributes to the possibility that patient position is a determining factor in catheterization of the left main stem bronchus.
**Limitations**

The sample was limited to:

1. Adult surgical patients.
2. Intubated patients with clinical indications for radiographic evaluation of the chest.
3. Patients hospitalized in one hospital.
4. Patients without anatomical abnormalities of the tracheobronchial tree which would change the position of the airway as determined by physical and radiographic examination.
5. Catheterizations performed by the investigator.

**Assumptions**

The following assumptions were made:

1. Owing to the normal anatomical configuration of the tracheobronchial tree, catheterization of the left main stem bronchus is more difficult than catheterization of the right main stem bronchus.
2. Catheterization of both bronchi is important for the adequate removal of secretions.
CHAPTER II

REVIEW OF THE LITERATURE

The management of secretions is very important to insure a patent airway. For a patient with an intratracheal tube, tracheobronchial suctioning of both the right and left main stem bronchi is necessary to remove secretions since indwelling endotracheal tubes not only increase the amount of secretions, but also reduce the patient's ability to cough explosively and clear his airway (Sanderson 1972).

Intratracheal Tubes

A wide variety of tubes is available for naso-tracheal or oro-tracheal placement. Each patient must be evaluated as to the type of tube which would best serve his needs. Each has special uses, advantages and disadvantages. Most are available with inflatatable cuffs near the tip of the tube. There is considerable variation in cuff design; one should be chosen that requires minimal inflation pressure, inflates evenly and uniformly over a broad area, and is composed of material which is neither irritating to tissue or subject to leakage. The tube is positioned to be above the carina but below the larynx (Sanderson 1972).

Positioning for Suctioning

Ochsner and Keller (1967) suggested that when a catheter is inserted into the trachea with the patient's head midline, it usually
enters the right main stem bronchus because the opening is in a more direct line with the lung. To facilitate entrance into either bronchi, the head and neck are turned to the side opposite the bronchus to be aspirated.

Secor (1969) indicated that to aspirate the left main stem bronchus, the patient's head should be turned to the right with the chin elevated and the chest turned to the left. She further stated that to aspirate the right main stem bronchus the patient's head should be turned to the left, with the chin elevated and the chest turned to the right.

Manipulation of the patient's head to the right facilitates entrance into the left main stem bronchus and manipulation of the head to the left facilitates entrance into the right main stem bronchus. This view is held by many authors discussing the importance of deep tracheobronchial suctioning (Abdellah, Kitchell and Meltzer 1969, American Journal of Nursing 1966, Bendixen et al. 1965, Kearns 1970, Safar 1965).

There is contradictory evidence based upon experimental data by Kirimli et al. (1970). Twelve patients were evaluated, to determine the accuracy of entering the predicted bronchus with both curve tipped and straight catheters, with and without the recommended head turning of the patient. Using the radiographic examination to determine catheter position, Kirimli et al. (1970) data is listed in Table 1.
Table 1. Straight catheter and curved catheter data.

<table>
<thead>
<tr>
<th>Position of Head</th>
<th>Straight Catheter</th>
<th>Curved Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right Lung</td>
<td>Left Lung</td>
</tr>
<tr>
<td>Rotated to Right</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>(tip to left)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotated to Left</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>(tip to right)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midline</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>(tip to left)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(tip to right)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER III

METHODOLOGY

Research Design

To obtain information on the significance of head position as a means of catheterizing the left main stem bronchus, the following design was undertaken. Since more often, due to the anatomy of the tracheobronchial tree, a suction catheter will enter the right main stem bronchus, the investigator attempted to test head positions which might result in catheterization of the left main stem bronchus. The midline position was used as a control to see if the patient would normally admit an object to the left or right main stem bronchus.

Population and Sample

The patient population was drawn from a metropolitan University Medical Center. All patients meeting the criteria were asked to participate. Patients consenting to participate were considered as volunteers for the study (see Appendix B). The Committee for Research on Human Subjects at the Medical Center approved the study.

Data Collection

The patient's head was placed in one of three different positions for each of three catheterizations. The positions were: (1) head midline, (2) head in maximal rotation to the right, and (3) head in maximal
rotation to the right and the neck hyperextended. Each patient was catheterized three times using a radiopaque catheter. (Example: One catheterization per patient for each treatment.) The order in which the catheterizations were done was randomized.

All catheterizations were performed by the investigator using the following technique. The patient was placed in a semi-fowler's position with the torso at approximately 45°. An x-ray plate was placed behind the patient's back in the correct position. The patient was first suctioned by the investigator in the routine manner to clear secretions from the large airways. He was then hyperoxygenated with 100% oxygen. If the patient was on the volume control respirator, in addition to the 100% oxygen given for one minute, he was sighed twice to hyper-inflate his lungs. Those patients not on a respirator were hyperoxygenated with a T-piece attached to the intratracheal tube for one minute. The patient's head position for catheter insertion was based on a predetermined routine for the three catheterizations utilizing a table of random numbers. A #16 red rubber straight catheter, 18 inches long, which is radiopaque, was inserted following the normal curve of the catheter with the investigator's dominant hand and held in place while the x-ray was taken.

**Analysis of the Data**

The data are submitted to a chi square technique utilizing a two by three contingency table and .05 significance level (Weinberg and Schumaker 1969, p. 261).
CHAPTER IV

CHARACTERISTICS OF THE SAMPLE

The sample consisted of nine men and three women. Their ages ranged from nineteen to seventy-five years.

The patient diagnosis fell into three categories. Four patients had abdominal surgery, five had open heart surgery and three had sustained traumatic injuries. Each patient's age, sex, and diagnosis with the type of intratracheal tube which was in place is listed in Table 2.
## Table 2. Patient characteristics.

<table>
<thead>
<tr>
<th>Pt. #</th>
<th>Sex</th>
<th>Age</th>
<th>Type of Tube</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>56</td>
<td>Naso-Tracheal</td>
<td>Revision of saphenous vein bypass graft.</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>56</td>
<td>Oro-endotrach.</td>
<td>Mitral valve replacement.</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>75</td>
<td></td>
<td>Repair of ruptured aortic aneurysm.</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>51</td>
<td></td>
<td>Appendectomy (ruptured appendix with peritonitis).</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>19</td>
<td>Tracheostomy</td>
<td>Gunshot wound to head Craniotony.</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>53</td>
<td></td>
<td>Gunshot wound to chest and epigastric region-Thorocotomy wound debridement, and expl. Laporotomy.</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>19</td>
<td>Oro-endotrach.</td>
<td>Revision of Tetralogy of Fallot.</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>69</td>
<td></td>
<td>Saphenous vein bypass graft left anterior descending coronary artery.</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>46</td>
<td></td>
<td>Multiple fractures-facial and ribs (auto accident).</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>36</td>
<td>Naso-Tracheal</td>
<td>Saphenous vein bypass graft to left ant. descending and right coronary arteries.</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>47</td>
<td>Oro-endotrach.</td>
<td>Revision of colostomy.</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>51</td>
<td></td>
<td>Repair of wound evisceration.</td>
</tr>
</tbody>
</table>
CHAPTER V

REPORT OF FINDINGS

Description of the Data

The individual results of the catheterizations of the twelve patients appear in Table 3. The midline position was used as the control. $R^1$ represented the position with the neck hyperextended and the head turned maximally to the right. $R^2$ represented the position with the head in maximal rotation to the right.

Patients 4, 5, 8, 9, 11, and 12 showed the catheter in the right main stem bronchus regardless of head position. The catheter was always in the left main stem bronchus for patients 6 and 10.

Patient 1 represented two experimental failures. In $R^1$ the investigator was not able to pass the catheter deeply enough and the catheter visualized high in the trachea on x-ray. In $R^2$ the naso-tracheal tube was resting on the carina preventing a suction catheter from entering either bronchus. According to the table of random numbers the order of treatment on this patient was $R^1$, midline, and $R^2$.

Patient 7 represented an experimental failure since a third film was not taken before the patient was extubated. The random order of the treatments was $R^1$, midline, and $R^2$.

In patient 2 the midline and $R^1$ position showed the catheter in the left bronchus. The $R^2$ position showed the catheter in the right bronchus.
Table 3. Individual results of three treatments.

<table>
<thead>
<tr>
<th>Patient #</th>
<th>Control</th>
<th>$R^1$</th>
<th>$R^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R</td>
<td>Failures</td>
<td>Failures</td>
</tr>
<tr>
<td>2</td>
<td>L</td>
<td>L</td>
<td>R</td>
</tr>
<tr>
<td>3</td>
<td>R</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>4</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>5</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>6</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>7</td>
<td>L</td>
<td>No Film</td>
<td>L</td>
</tr>
<tr>
<td>8</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>9</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>10</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>11</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>12</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>
With patient 3 the catheter did enter the left main stem bronchus when the head was rotated to the right while the midline position catheterization showed the catheter entering the right main stem bronchus. This was the only patient who showed selectivity of entrance dependent on head position.

Patients 5 and 6 had tracheostomies with tubes of the Portex type sizes 11 and 12. Patients 1 and 10 had naso-tracheal tubes sizes 9 and 8 respectively. The other patients had oro-endotracheal tubes with sizes varying from 7.5 to 9 millimeter internal diameter. There were no instances where the tube was changed during the period of time the treatments were done. There appeared to be no difference in the results which could be attributed to the type of tube the patient had.

The raw data were submitted to a chi square analysis. A two by three contingency table was used (see Table 4). The hypotheses were tested at the .05 significance level and determined not statistically significant. The hypotheses were not accepted.
Table 4. Chi square two by three contingency.

C = control head midline, R\(^1\) = neck hyperextended and turned maximally to the right, R\(^2\) = head turned maximally to the right. (Note: 3 experimental failures).

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>R(^1)</th>
<th>R(^2)</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Right Main</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stem Bronchus</td>
<td>8 (67%)</td>
<td>6 (60%)</td>
<td>7 (64%)</td>
<td>21</td>
</tr>
<tr>
<td><strong>Left Main</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stem Bronchus</td>
<td>4 (33%)</td>
<td>4 (40%)</td>
<td>4 (36%)</td>
<td>12</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>12 (100%)</td>
<td>10 (100%)</td>
<td>11 (100%)</td>
<td>33</td>
</tr>
</tbody>
</table>

\(\chi^2 = .12\)

\(\chi^2\) ns

\(p > .25\)

\(z = .5\)
CHAPTER VI

DISCUSSION OF FINDINGS

The data from the study did not substantiate the use of head position as a method for selective catheterization of the left main stem bronchus. As Krimli et al. (1970) also found, positioning the patient's head for selective catheterization with a straight catheter seemed to be ineffective.

In light of the data, teaching nurses that head position facilitates entrance into a given bronchus is questioned. Apparently it is impossible to predict which bronchus is entered utilizing head position as the indicator. Fluroscopy or radiographs determine which bronchus is to be catheterized. In routine tracheobronchial suctioning there is no x-ray done so the nurse is "treating the patient blindly", with no knowledge of which bronchus is being catheterized.

Assuming that the reason for tracheobronchial suctioning is to clear airways of secretions and maintain a patent airway, perhaps the nurse would be more effective in accomplishing this if she devised an alternative method. Adequate hydration to keep secretions loose, postural drainage with percussion and vibration, and positioning the patient to facilitate draining the secretions from the lower lobes up into the high airways would be helpful. Secretion should then be in the trachea where they can be reached easily without concentration on selective bronchial catheterization.
While Kirimli et al. (1970) showed that curved catheters increase the rate of selective catheterization, the catheters may be more difficult to use. The catheter may be difficult to pass in an intratracheal tube of small diameter or with a sharp angle. Discomfort to the patient may be increased if the curved portion, which is of harder material than a soft catheter, contacts the soft airway tissues.

Turning the patient's body far to the left when attempting to selectively catheterize the left main stem bronchus may increase the frequency with which the catheter enters the left main stem bronchus due to gravitational force. Similarly, turning the patient to the right should aid catheterization of the right main stem bronchus.

If selective catheterization of a bronchus is necessary, a fibroscopic bronchoscopy can be done in the patient's room with relatively few dangers and discomforts. Through selective catheterization of each bronchus, frequent suctioning may often be eliminated resulting in less trauma to the mucus membrane. The patients should have fewer episodes of hypoxia due to removal of oxygen from the trachea with a suction catheter. Fibroscopic bronchoscopy is currently done primarily by the physician but nurses are beginning to assume this responsibility with instruction.

Two questions remain unanswered. First, is the anatomy of the patient a factor that influences which bronchus the catheter enters? In eight out of twelve patients the catheter went into the same bronchus on all three treatments. Second, is the position which the endotracheal tube is pointed a factor influencing which bronchus is entered? It is
difficult if not impossible, to determine radiographically which direction the endotracheal tube is pointed.
CHAPTER VII

SUMMARY

Management of secretions is very important in the maintenance of a patent airway. For the patient with an intratracheal tube, tracheobronchial suctioning of both the right and the left main stem bronchi is necessary to remove secretions because indwelling intratracheal tubes not only increase the amounts of secretion but reduce the patient's ability to cough and clear his airway.

This study was designed to evaluate the effectiveness of manipulating patients head position to facilitate selective catheterization of the left main stem bronchus.

Traditional theory is that head position effects which bronchus the suction catheter enters. However, there is no experimental data to support the theory. Only one study has experimental data supporting its conclusions. Interestingly enough, the data indicated that proper head position was not effective in selective catheterization of a main stem bronchus (Kirimli et al. 1970).

The theory that manipulation of patient position could be utilized to significantly improve catheterization of the left main stem bronchus was the basis for this study. Three specific positions for catheterization were used. One position, the control, was with the head midline. The second position was with the head in maximal rotation to
the right. The third was with the neck in hyperextension and the head turned maximally to the right. Radiographic determination of catheter position was utilized. The findings were submitted to a chi square analysis using a two by three contingency table and .05 significance level. The data were not statistically significant.

As Kirimli et al. (1970) also found, positioning the patient's head for selective catheterization seemed to be ineffective. In light of this data, it appears that teaching nurses head position facilitates entrance into a given bronchus is incorrect.

Alternative methods to clear the tracheobronchial tree should be attempted. Percussion and vibration, and postural drainage to facilitate raising material from the lower lobes into the higher airways could aid the nurse in removing secretions from the trachea without selective bronchial catheterization. Fibroscopic bronchoscopy insures selective catheterization of the right or left main stem bronchus and should result in less trauma to the mucus membrane than frequent tracheobronchial suctioning.

The following implications for further study are suggested:

(1) A study to determine the direction which an endotracheal tube is pointing when a patient is catheterized to discover if it effects which bronchus the catheter enters.

(2) A study utilizing head positions to facilitate entrance into the right main stem bronchus.

(3) A study using curved catheters to suction the patient without positioning the head in any given position.
(4) A study turning the patient's whole body far to the left side to facilitate entrance into the left main stem bronchus and far to the right side to facilitate entrance into the right main stem bronchus.
APPENDIX A

PATIENT INFORMATION SHEET

I. Patient profile

Age:
Sex:
Race:
Diagnosis:
Other anatomic and medical factors affecting the respiratory system:

II. Patient Categories

1. Operative procedure:
2. Non-operative:
3. Intubated patient:
   a. Endotracheal:
   b. Naso-tracheal:
   c. Tracheostomy:

4. Type of Tube:
   a. External diameter:
   b. Internal diameter:

III. Clinical Indication for Suctioning

IV. Individual Results

1. Head Position
   a. Midline:
   b. Rotated to the Right:

2. Neck hyperextended - head rotated to the right.
APPENDIX B

FORM USED FOR PATIENT CONSENT
PATIENT CONSENT

LAY SUMMARY

In order to provide proper care when you have a tracheostomy tube (a metal tube in your windpipe) in place it is necessary repeatedly to suction out mucus from the large airways communicating with your lungs. Chest X-Rays also are ordered frequently for the purpose of early detection of infection due to plugging of airways. The purpose of this study is to determine whether the suction catheter adequately clears all the large airways. For this purpose a special radiopaque catheter (one which can be seen in X-Ray) will be used for suctioning. At the time of your routine X-Ray examine you will be suctioned to clear your large airways. After the suctioning the radiopaque catheter will be inserted and taped to your cheek. The chest X-Ray will then be taken and the position of the catheter can be determined accurately. This information will be helpful in assuring proper drainage of your lungs and in establishing improved procedures of caring for patients with similar problems. As the procedures (suctioning and X-Ray) are routine in your case, there will be no significant risk, except for the slight discomfort when the catheter is taped to your cheek to fix it in position for the X-Ray. If you do not choose to participate in this procedure you will be cared for in the routine manner.

PROTOCOL REQUIREMENTS (circle applicable items).

Use reverse side if additional space is needed.

1. Collection of blood, urine, stool, other (specify) and number of specimens
2. Administration of drug (route, effects)
3. Performance of proc. (biopsy, other)
4. Restriction of activity
5. Restriction of diet
6. Length of time for study

EXPLANATION

The nature and requirements of the study have been clearly explained to me by the investigator and I understand the purpose of the protocol and its possible benefits and risks.

Patient's Signature

Investigator's Signature

Date
REFERENCES


