**ADENOTONSILLECTOMY: CARE GIVERS’ RECALL OF INFORMATION ON RISKS PROVIDED DURING INFORMED CONSENT PROCESS**

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**ABSTRACT**

**Background:**

“Informed consent” for surgery has been widely researched; however, there is no local data on surgical risk recall by care givers’ (usually a parent) of children undergoing adenotonsillectomy (Ts &A).

**Aim and Objective**

This study evaluated care givers’ recall of the surgical risks for Ts&A after verbal explanation compared to combined verbal and written explanation in the informed consent process.

**Design of the study**

This was a prospective randomized comparative study of fifty parents/guardians of patients undergoing tonsillectomy and adenoidectomy for obstructive sleep disorders.

**Setting**

The E.N. T. Unit, Korle Bu Teaching Hospital, Accra, Ghana.

**Materials and Methods**

Parents/guardians of children were randomized to only verbal explanation or combined verbal and written explanations prior to signing informed consent a day before their wards’ operation. Recall of surgical risks explained in the informed consent procedure was evaluated two days postoperatively. The rates of surgical risk recall for the two groups were analysed and compared.

**Results**

Fifty-eight parents were randomised but 50 completed the study, 22 in the verbal only group and 28 in the combined verbal and written group. There were no significant differences in the demographic characteristics of the parents/guardiansThere were no significant differences in the demographic characteristics of the parents/guardians. The overall recall rate for surgical risks for the whole group was 46.0%. The surgical risk recall rate for the verbal explanation group, 44.4% was not significantly different from that for the combined verbal and written explanation group, 47.2% (p=0.624). There was a weak but significant positive correlation between risk recall scores and parental level of education (Spearman rs=0.306; p = 0.015).

**Conclusion**

Among parents/guardians whose children were undergoing adenotonsillectomy, combining written explanation with verbal explanation in the informed consent process did not significantly improve postoperative surgical risks recall rate when compared with only verbal explanation. The overall risk recall rate was 46.0%. A study with larger sample sizes is recommended to confirm these findings.

**Key words**

Informed Consent, Adenotonsillectomy, Surgical Risk Recall, Verbal Explanation, Written Explanations.

**Introduction:**

Informed consent for adenotonsillectomy means seeking permission from the care giver (who is usually a parent) of the patient for this surgical intervention. The caregiver is provided with all the information on the intervention including the benefits and side effects and alternate options of the treatment. Following this the caregiver grants permission for the intervention to be carried out, taking into consideration all the information provided.

The subject of informed consent for patients undergoing surgical interventions has been widely researched. 1- 4 However, there are relatively fewer publications on informed consent for patients undergoing paediatric surgical operations.

The methods of informed consent vary from centre to centre. It may be administered by verbal explanation in which there is verbal provision of all the needed information to patients. In some centres written information is provided to patients and in other institutions informed consent is obtained after a combination of written and verbal explanation. Furthermore, there is variation in the seniority of the practitioners who administer the informed consent for surgery. In our institution the most senior postgraduate trainee is tasked with obtaining informed consent whereas in other centres as a policy, informed consent is obtained by the most senior practitioner in charge of the patient’s surgical operation.

Paediatric patients are unable to provide informed consent and therefore, their care givers, who are usually parents or guardians do so on their behalf.

Pioanosi et al5 observed that overall parental recall of risks associated with common paediatric otolaryngology procedures was only 30%. They advocated for methods to improve parental recall.Papsin et al6 noted that caregiver risk recall in paediatric otoplasty was 40% compared to 55.7% with the addition of written information provided during the informed consent process.

Nadeau et al7 observed that parents of children undergoing ear, nose, and throat surgery recall 57.5 % of counselled risks. They therefore, recommended the use of more time to set parents’ minds at ease during the process of informed consent counselling in order to improve measured parental understanding of surgical risks. Furthermore, these researchers noted that maternal parents’ recalled risks were significantly better than the paternal parent. In addition, they also observed a negative correlation (inverse relationship) between parental education and risk recall score, with parents with lower education levels scoring higher on both the preoperative and the postoperative surgical risk recall.

Li et al8 concluded in their studies that there was 28.6% parental retention of verbal information provided during emergency operative consent and advocated that proper documentation of this process was essential.

In order to improve recall of content, Kam et al9 demonstrated that preoperative phone counselling by junior medical doctors significantly improved recall of surgical risks to 71% for tonsillectomy and reinforces informed consent provided by the senior consultant.

Batuyong et al10 recommended the use of a computer based, patient controlled, interactive multimedia educational tool on knowledge transfer and patient learning of information specific to bunion deformity surgery to enhance patient knowledge and understanding of informed consent for this surgery.

Informed consent in the ENT Department of the Korle Bu Teaching Hospital is given after verbal explanation. There is no local data on how much of the surgical risk parents or care givers of patients undergoing adenotonsillectomy understood and could recall. Additionally, there is no local data on the most effective method of giving informed consent for adenotonsillectomy. The benefit of verbal explanation supplemented by written explanation is unknown for care givers of patients undergoing adenotonsillectomy and there is no local data on the effect of parental demographic factors.

This study therefore aimed at evaluating care givers’ recall of the surgical risks for adenotonsillectomy after verbal explanation compared with combined verbal and written explanations prior to providing informed consent.

**Patients and Methods**

This was a prospective randomised comparative clinical audit of parental recall of surgical risks following informed consent for adenotonsillectomy. This study was carried out from 1st March 2017 to 31st May 2018 at the E.N.T. Unit of the Korle Bu Teaching Hospital in Accra, Ghana. This centre serves as a major tertiary care centre for referrals for E.N.T. patients from secondary and primary health care centres in Ghana. This centre also serves as an ENT training facility for undergraduates and postgraduates.

The subjects for this study were caregivers of the children who were listed for adenotonsillectomy for obstructive sleep disorder (OSD) following failed medical therapy.

Parents or care givers who consented for their children to have adenotonsillectomy for OSD and were willing to take part in the study were included. They signed an informed consent to participate in the study. The demographic data of care givers including age, gender, race and the highest educational level achieved were recorded.

A convenient sample size of 50 was used based on a similar study9 in which a sample size of 43 was used made up of 25 control group and 18 study group. Consecutive subjects were randomized using a ballot system format in which each subject picked a rolled piece of paper from a ballot box. The piece of paper had an inscription of either an odd or even number. Subjects who picked odd numbers were assigned to the verbal explanation study group and those who picked even numbers were assigned to the combined verbal and written explanation study group. To avoid biases, the randomization was supervised by a resident doctor at the study site who was not a member of the study team. The first group had a verbal explanation before informed consent was signed on the day before adenotonsillectomy. The procedure to be carried out was explained to them including the benefits and complications associated with the procedure.

The common surgical risks discussed verbally during the informed consent process were as follows; blood loss, minor injury to the teeth or tongue or other structures in the mouth, painful throat, voice changes, velopharyngeal insufficiency, bleeding a few days after discharge from hospital, infection of site of operation, lack of adequate fluid intake leading to dehydration, failure to provide cure /correct the patient's condition.

The second study group of care givers had verbal explanation and in addition were also provided with a written explanation of the common surgical risks for adenotonsillectomy to study (Appendix 1). They also signed an informed consent after having had enough time to study the written explanation.

For each participant in each group, the number of items recalled (out of 9, the risk recall score) was determined and the mean calculated for the group. In addition, the risk recall rate, defined as the total score of the group divided by the maximum possible score for that group, multiplied by one hundred, was determined.

Recall of surgical risks (SR) for both groups was evaluated two days postoperatively (Appendix 2). The patients were discharged after the SR evaluation on the second post-operative day.

*Statistical analysis:*

Statistical analysis was done using the IBM SPSS Software version 20. Numeric variables were summarised and presented as mean and standard deviation. Categorical variables were presented as percentages. Numeric variables were compared using student t-test; categorical variables were compared using chi square test. Spearman’s correlation coefficient was used to determine relationships between risk recall scores and age of parent/care giver and level of education. Differences were considered significant if p was less than 0.05.

The study protocol was approved by the Institutional Review Board of the Korle Bu Teaching Hospital (ID NO. KBTH000066/2016).

**Results**

A total of fifty-eight (58) parents/care givers were initially recruited for the study but eight patients could not complete the study. The eight parents/care givers (seven from the verbal explanation group and one from the combined verbal and written group) were not available to participate in the post-operative evaluation due to domestic emergencies. Even though eight other care givers were available to deputize for them, they could not meet the criteria for the study. Therefore fifty (50) parents/care givers made up of forty- eight females and two males completed the study. Twenty-two (22) participants had verbal explanation and twenty-eight (28) had a combination of verbal and written explanations prior to signing informed consent.

The mean age of the subjects was 36.2(SD5.8) years with a range of 23 to 58 years. Those who had had tertiary level education formed the largest group, 22 (44.0 %). There were no significant differences in the demographic characteristics of the two groups, (Table 1). The mean risk recall score for the verbal explanation group and the verbal and written explanations group were 4.0 (SD1.3) and 4.2 (SD1.7) respectively. There was no statistically significant difference between the two (p=0.650) (Table 2). The overall risk recall rate for all subjects was 46.0 %; the recall rate for the verbal explanation group was 44.0% and that for the combined verbal and written explanations group was 47.2%; the difference was not statistically significant (p=0.624). Analysis of the association between demographic characteristics and risk recall score showed a weak but significant positive correlation between risk recall score and parental education level (Spearman rs=0.306; p = 0.015). There was a very weak negative and non-significant correlation between risk recall score and age of parent/care giver (Spearman rs = -0.149; p = 0.151). The commonest surgical risks recalled by parents/care givers of both groups were bleeding and minor injuries to tongue and teeth. The least commonly identified in each of the two groups was “lack of adequate body fluid”.

**Discussion**

This is our first local study of informed consent in paediatric adenotonsillectomy. There were more maternal parents (96%) than the paternal parents (4%), similar to the findings of Nadeau et al7. The commonest surgical risk recalled were bleeding, minor injury to the teeth and other structures in the mouth and bleeding post-discharge. Our findings were similar to those of Ferius-Tores et al11 who noted that patients will usually remember complications that appear serious and life threatening.

The overall risk recall rate for all subjects was 46.0%, similar to the results of Henry et al12 who had an overall risk recall of 43% but less than that of Nadeau et al7 (57% overall risk recall rate). The absence of any significant difference between the risk recall rates of the two groups is consistent with the findings of Papsin et al6. The lack of any significant difference may be due to a high quality of verbal communication or lack of improved understanding of the written communication over the verbal. It is also possible that the sample sizes were not large enough to have detected real differences.

The surgical risk recall rates with the use of surgical risk information sheets have shown mixed results. Some studies have shown that surgical risk handouts can improve patient recall.13 However, Dawes 14, Kerrigan et al15, Hekkenberget et al16, Brown et al17 and Stanley et al18 found no statistically significant improvement in surgical risk recall with the use of surgical risk information sheets, consistent with our results.

Our findings have demonstrated that supplementing verbal explanation with written information does not improve recall of risks explained in the process of obtaining informed consent. There is the need for studies with larger sample sizes to confirm or refute these findings. Until that has been done the ENT department may have to continue with its current practice of using only verbal explanations before informed consent is obtained for paediatric adenotonsillectomy. In order to improve recall rate in the department, more time should be spent to set parents’ minds at ease during the process of verbal explanation prior to obtaining informed consent. Future studies should also focus on evaluation of risk recall using verbal explanations which commence at the outpatient clinic and are repeated a number of times prior to admission for adenotonsillectomy.Whatever may be the method of explanation used, meticulous documentation of content of the explanation in patients’ records is crucial evidence in medicolegal defence as most parents are unable to recall most of the content of explanations given.

The findings of a weak but significant positive correlation between risks recall scores and level of education is in contrast to the findings of Nadeau et al. They observed a negative correlation between risk recall scores and level of education. Their findings were due to confounding factors in the subjects with lower education who had had military training. The findings of a weak but significant positive correlation between risks recall scores and level of education in our study may be due to the small sample sizes of the groups studied. A larger sample size may present a true reflection of the relationship between the two variables.

The limitation of this study is our inability to control the attrition rate of parents/care givers due to unforeseen domestic emergencies. This resulted in significant disparity in the sample sizes in the arms of the study.

**Conclusion:**

There was no statistically significant difference in parental information recall of key surgical risks for adenotonsillectomy between verbal explanation and the combination of verbal and written explanations prior to obtaining informed consent. The overall risk recall rate was 46.0%. There was a weak but significant positive correlation between risk recall scores and parental level of education. A study with larger sample sizes is recommended to confirm these findings.

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**Table 1: Background characteristics of care givers of patients for adenotonsillectomy**

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| **Characteristics Verbal Verbal + written Total P-value** **Explanation Explanation** **N (%) N (%) N (%)**  |

**Age,**

**Mean(SD) years** 36.4(5.9) 36.0(5.9) 0.813\*

**Sex:**

Male - 2 (7.1) 2 (4.0)

Female 22 (100.0) 26 (92.9) 48 (96.0)

Total 22 (100.0) 28 (100.0) 50 (100.0) 0.497**@**

**Education:**

None 1(4.5) 1(3.6) 2(4.0)

Primary 1 (4.5) 1 (3.6) 2 (4.0)

J.H.S 3 (13.6) 2 (7.1) 5 (10.0)

S.H.S 6 (27.3) 11 (39.3) 17 (34.0)

Vocational 1 (4.5) 1 (3.6) 2 (4.0)

Tertiary 10 (45.5) 12 (42.9) 22 (44.0)

Total 22 (100.0) 28 (100.0) 50 (100.0) 0.950**@**

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| \*Student t-test **@**Chi Square test  |

**Table 2: Care giver information recall of key surgical risks for adenotonsillectomy between verbal explanation and verbal and written explanations**

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| **Surgical risks Verbal Explanation Verbal + written Explanation p-value** **N (%) N (%)** |
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**Risks:**

\*Immediate bleeding 20 (90.9) 25 (89.3) 0.849

Bleeding a few days

after discharge 17 (77.3) 19 (67.9) 0.462

Painful throat 11 (50.0) 17 (60.7) 0.449

Infection 6 (27.3) 10 (35.7) 0.525

Lack of adequate body fluid 1 (4.5) 3 (10.7) 0.425

Failure to provide cure 4 (18.2) 4 (14.3) 0.709

ǂ Minor injury 13 (59.1) 17 (60.7) 0.907

Voice changes 10 (45.5) 14 (50.0) 0.749

Nasal regurgitation 6 (27.3) 10 (35.7) 0.525

Total 88 (44.4) 119 (47.2) 0.690

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| \*Immediate bleeding within 24 hours of operation. ǂ Minor injury to the teeth or tongue or other structures in the mouth. Mean score for verbal explanation = 4.0 (SD 1.3). Mean score for verbal and written explanations = 4.2(SD 1.7).Risk recall rate for Verbal Explanation = [88/198] X 100% = 44.4%Risk recall rate for Verbal and Written Explanations = [119/252] X 100% = 47.2%Overall Risk Recall Rates for the two groups combined = [(88+119)**/**450] X 100% = 46.0% |

**APPENDIX I**

**SURGICAL RISKS FOR ADENOTONSILLECTOMY INFORMATION**

Dear Parent/Care Giver,

Your child has disturbance of sleep and will require removal of some tissues in the throat called the tonsils and adenoids. The operation is an adenotonsillectomy. This operation is the treatment for this condition. However, there are a few surgical risks which should not frighten you as all precautions are taken to avoid most of these risks. These surgical risks hardly occur in most patients we have so far operated on. You should however be aware of these risks to enable you take a consent for Adenotonsillectomy. The surgical risks are:

1. Blood loss - this can happen a few hours after the operation. We are able to stop this blood loss.
2. Bleeding can occur a few days after discharge from hospital (this occurs if patient refuses to eat - our patients are normally discharged when they are able to feed adequately).
3. Painful throat (we will administer pain killers to address this problem).
4. Infection of site of operation (this occurs when patient is unable to feed very well). We prevent this by administering adequate potent pain-relieving medications to enable patient feed without pains in the throat.
5. Lack of adequate body fluid. (dehydration): This occurs when patient refuses to take in sufficient water and food (we prevent this by encouraging adequate intake of fluids and feed)
6. Failure to provide cure /correct the patient's condition, (in a few cases this may be due to other conditions that must be identified and addressed).
7. Minor injury to the teeth or tongue or other structures in the mouth, (this is a preventable problem and we take always the needed precautions against it).
8. Voice changes - the voice may have a nasal tone, (this improves given time).
9. Velopharyngeal insufficiency - this means that when patient feeds part of feed may come out through the nose (we prevent this by examining patient for defect in the roof of mouth (palate) under anaesthesia before the operation).

**APPENDIX II.**

**Evaluation of surgical risk recall questionnaire – on the 2nd post-operative day.**

ANSWER THE FOLLOWING QUESTIONS WHICH ARE RELATED TO SURGICAL RISKS FOR THE OPERATIVE TREATMENT OF YOUR CHILD WHICH WERE DISCUSSED WITH YOU AT THE ENT CLINIC.

**Please provide a YES answer or NO answer to the following questions.**

Do you remember the following surgical risks of Adenotonsillectomy?

1. Immediate bleeding within 24 hours of operation.

2. Bleeding a few days after discharge.

3. Painful throat.

4. Infection.

5. Lack of adequate body fluid. (dehydration)

6. Failure to provide cure /correct the patient's condition

7. Minor injury to the teeth or tongue or other structures in the mouth,

8. Voice changes - the voice may have a nasal tone

9. Nasal regurgitation (when patient feeds part of feed may come out through the nose)