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Original Article

Comparative study on Post Tonsillectomy use of Antibiotics and Placebo

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Abstract:

Tonsillectomy is the most frequently performed surgical procedure in Otolaryngological practice. We included 110 patients and divided into antibiotic group and placebo group, and followed up upto 7th POD. Parameters of observation were pain, fever, nausea & vomiting, reactionary & secondary haemorrhage, duration of hospital stay and return to normal diet. The result of this study showed that post operative pain and return to normal diet improved in antibiotic treated group than those who received placebo, but there is no statistically significant difference between two groups in respect of fever, nausea & vomiting, reactionary & secondary haemorrhage and duration of hospital stay.

Keywords: *Tonsillectomy, Bleeding, Pain, Antibiotic.*

Introduction:

Tonsillectomy, whether or not combined with adenoidectomy is one of the most common frequently performed surgical procedures in the world, with higher prevalence among the pediatric population. The main current indications for tonsillectomy and adenotonsillectomy are recurring infections and blockages of the upper airways, which may possibly lead to serous otitis, repetition otitis media, rhinosinusitis, snoring, sleep apnea that often compromising the child's development and performance at school.[1]

There have been great developments in the surgical field in the form of surgical technique and anesthesia, but postoperative morbidity is yet an important factor to be considered. Several papers have looked into drugs to minimize postoperative morbidity, such as steroids administered during anaesthesia or postoperative analgesics such as paracetamol, diclofenac and tramadol, and postoperative antibiotics[1] .

The most significant post tonsillectomy morbidity arises from bleeding and pain. Secondary haemorrhage is now more common than primary and particularly so in adults. The exact cause of post tonsillectomy haemorrhage is not still clear but commonly attributed to infection.[2] Antibiotics are frequently prescribed in the perioperative and post-operative time periods since many of the

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previously signs and symptoms are thought to be due to infection.[3]

Although some studies have shown antibiotics to be beneficial in reducing post-tonsillectomy morbidity, there is still no consensus on the matter.[1] For the past 18 years, investigators have analyzed the use of antibiotics to reduce post-tonsillectomy morbidity, showing no clear consensus. Results of randomized studies have demonstrated conflicting results; with some showing a clinical benefit, whereas others demonstrated no benefit.[4] Specially in terms of haemorrhage there is very little clinical evidence to support the use of post-tonsillectomy antibiotics in reducing haemorrhage. A retrospective study by Ranjit et al with children who underwent adenotonsillectomy and a study by O'Reilly et al. with adult patients showed that post-tonsillectomy antibiotics did not reduce the incidence of bleeding episodes. In a study, Ahsan et al. suggested that clinical signs of infection are lacking in patients with secondary tonsillectomy bleeding. Correspondingly, the routine use of antibiotics should be questioned for secondary tonsillectomy haemorrhage. In fact a number of studies has demonstrated that the use of prophylactic antibiotics has no effect on the subsequent complications rate.[5] However the widespread use of antibiotics is not always benign, as treatment may result in allergic reaction, anaphylaxis, diarrhea, nausea and vomiting and the chance of increase antibiotics resistance.[2]

Materials and Methods:

This study was a double blind randomized control trial conducted at the Department of Otolaryngology and Head-Neck surgery of Dhaka Medical College Hospital, Dhaka, between the period of November 2007 to October 2008.The patients admitted in the Department of Otolaryngology and head Neck surgery of Dhaka Medical College Hospital for tonsillectomy operation during the study period and who fulfills the inclusion criteria. 110 subjects were include in the study.Tonsillectomy was done by dissection method under general anaesthesia with endotracheal intubation. Haemostasis was done by Electro coagulation and Ligation.

Antibiotic Therapy:

After admission, the patients were being allocated into two groups by coin flipping method. Both groups received inj. Cefradineperoperatively(15mg/kg body wt.) The case group received Placebo (A capsule that resemble antibiotic capsule but not antibiotic) whereas control group received antibiotic Cefradine (15mg/kg body wt.) in post-operative period for 7 days. Other supporting treatment is same for both groups such as analgesics (Paracetamol thrice daily and Diclofenacsodium if required), antiseptic mouthwash (diluted Hydrogen peroxide)

Data Collection:

Relevant data were collected in a pre designed data collection sheet for each of the patient admitted in Dhaka Medical College Hospital Dhaka admitted for Tonsillectomy operation. Informed consent were obtained from the patient him or herself or from the legal guardian of the patient prior to entry into the trial. The patients were randomly allocated into two groups by coin flipping. Control group received a week of Cefradine post-operatively and case group received placebo. Doses were according to the British National Formulatory 1996 edition and were followed up at 1st, 2nd 3rd, 5th, 7th postoperative day. During each visit they were subjected to routine examination such as examination of the tonsillar fossa, temperature, pulse rate. The subjective and objective evaluations were carried out by asking the patients whether the symptoms are present or not. Data were collected in terms of demographic and clinical variables. Pain was assessed by Visual analogue Pain Scale .

Operational Definition :

1. Antibiotic group: Patients who were given antibiotic Cefradine after tonsillectomy in this study. (N=58)
2. Placebo group: Those who received a capsule which was resembles to antibiotic but not antibiotic. In this study capsule vitamin B complex was used as placebo. (N=52)

Result:

Table-I

Distribution by indications for Tonsillectomy.

Indication	Number	Percentage
Chronic Tonsillitis	92	83.64
Hypertrophied Tonsils	16	14.55
History of peritonsillar Abscess	02	01.82
Total	110	100.00

Table –II

Pain in 5th postoperative day.

	Group		Total
Pain	Placebo N-52 (%)	Antibiotic N-58 (%)	
No pain	05(9.61)	18(31.03)	22(20)
Mild	30(57.69)	24(41.37)	55(50)
Moderate	17(32.7)	16(27.6)	33(30)
Total	52(100)	58(100)	110(100)

Table –III

Pain in 7th postoperative day.

	Group		Total
Pain	Placebo N-52 (%)	Antibiotic N-58 (%)	
No pain	9(17.3)	20(34.5)	29(26.3)
Mild	30(57.7)	33(56.9)	63(57.3)
Moderate	13(25)	05(8.6)	18(16.4)
Total	52(100)	58(100)	110(100)

Table-IV

Comparison of Fever.

Fever	Placebo N-52 (%)	Antibiotic N-58 (%)	Total
Day-1	20(38.5)	19(32.8)	39(35.5)
Day-2	02(3.8)	02(3.4)	04(3.6)
Day-3	02(3.8)	0(0)	02(1.8)
Day-5	03(5.8)	0(0)	03(2.7)
Day-7	06(11.5)	02(3.4)	08(7.3)

Table –V

Comparison of Nausea/Vomiting

Nausea/ Vomiting	Placebo N-52 (%)	Antibiotic N-58 (%)	Total
Day-1	16(30.8)	21(36.2)	37(33.6)
Day-2	04(6.9)	02(3.8)	06(5.5)
Day-3	0(0)	0(0)	0(0)
Day-5	0(0)	0(0)	0(0)
Day-7	0(0)	0(0)	0(0)

Table-VI

Comparison of the condition of Tonsillar Fossa

Tonsiller Fossa	Placebo N-52 (%) Healthy	Placebo N-58 (%) Unhealthy	Antibiotic Healthy	Antibiotic Unhealthy	Total
Day-1	49(94.2)	03(5.8)	55(94.8)	03(5.2)	06(5.5)
Day-2	52(100)	0(0)	58(100)	0(0)	0(0)
Day-3	52(100)	0(0)	58(100)	0(0)	0(0)
Day-5	49(94.8)	03(5.2)	58(100)	0(0)	03(2.7)
Day-7	47(90.4)	05(9.6)	56(96.2)	02(3.8)	07(6.4)

Table-VII
Mean Comparison of Return to normal diet

	Group	N	Mean (Days)
Return to	Placebo	52	4.34
normal diet	Antibiotic	58	4.05

Table-VIII
Mean comparison of duration of hospital stay

	Group	N	Mean (Days)
Hospital	Placebo	51	2.57
stay	Antibiotic	58	2.45

Table –IX
Comparison of reactionary haemorrage.

	Study group		Total
Reactionary haemorrage	Placebo N-52 (%)	Antibiotic N-58 (%)	
No	50(96.2)	57(98.3)	107(97.3)
Yes	2(3.8)	1(1.7)	03(2.7)
Total	52(100)	58(100)	110(100)

Table –X
Comparison of secondary haemorrage.

	Study group		Total
Secondary haemorrage	Placebo N-52 (%)	Antibiotic N-58 (%)	
No	51(98.1)	57(98.3)	108(98.2)
Yes	01(1.9)	01(1.7)	02(1.8)
Total	52(100)	58(100)	110(100)

Discussion:

Out of 110 (52+58) patients, 55(50%) were male and 55(50%) were female. On age distribution Mean Age of the patients of placebo group was 18.15±7 years and the mean age of the patients of antibiotic group was 18.81±6.72 years. Mean age of the respondents was 18.50±6.92 years Out of 110 patients the most common indication for the patients who had undergone for tonsillectomy was chronic tonsillitis (83.64%). Next Hypertrophied tonsils (14.55%) causing symptoms.

Regarding the comparison of pain on the 1st, 2nd and 3rdpost-operative day in placebo or no antibiotic group and antibiotic group found statistically insignificant. On the 5th post-operative day 5 patients from placebo or no antibiotic group and 18 patients from antibiotic group had no pain. 30 and 17 patients from placebo group and 24 and 16 from antibiotic group of experienced mild and moderate pain respectively. On comparison between placebo group and antibiotic group, antibiotic group was found better than placebo group. P value was 0.02. That is statistically significant. It indicates that pain significantly reduces in the patients who took antibiotic after tonsillectomy. On the 7th day in placebo group 9(17.3%) patients had no pain, 30(57.7%) had mild pain, 13(25%) had experience moderate pain. And in the control group 20(34.5%), 33(56.6%) and 5(8.9%) patients experienced no pain, mild pain and moderate pain respectively. Pain was found statistically significant. Statistical analysis shows that postoperative pain in antibiotic group significantly reduced from 5th/7th postoperative day than those who received placebo. MP Colvery et al. demonstrated that postoperative pain and analgesics consumption were significantly higher in non-antibiotic treated patients.[6]

Three studies reported results regarding this outcome. Only one of these studies done by SA Telian et al demonstrated that the use of perioperative antibiotics was associated with a significant reduction in the number of patients experiencing postoperative fever. Another two studies done by CR Cannon and JR Grandis et al. found no association between use of antibiotic and postoperative fever[7].

16 patients who did not received antibiotic post-operatively and 21 who received antibiotic had either nausea or vomiting. It was statistically insignificant. 81% of the total patients who had nausea or vomiting were female, it indicates that post-operative nausea and vomiting is significantly higher in female. Two studies reported results regarding the incidence of nausea and vomiting. WC Lee et al. and BE Lindenet al. found no significant difference in the incidence of nausea and vomiting between antibiotic treated patients and patients who did not receive antibiotics during the perioperative period.[8]

Examination of the tonsillar fossa was done on 1st, 2nd, 3rd, 5th and 7th postoperative day. On 1st postoperative day tonsillar fossa of 3 patients in each groups found unhealthy. On the 5th day 3 patients from placebo group developed unhealthy tonsillar fossa and on 7th day it was 5. In the antibiotic group tonsillar fossa of 2 patients were found unhealthy on 7th postoperative day. 3 patients who received placebo had unhealthy tonsillar fossa on 1st postoperative day and 3 patients had unhealthy tonsiller fossa on the 5th post-operative day . 1 patient had developed secondary haemorrhage.

2 (3.8%) patients of placebo group and 1 (1.7%) of antibiotic group had developed reactionary haemorrhage. And one patient from each group developed secondary haemorrhage. While comparing the two groups it was found statistically insignificant. Total reactionary haemorrhage was 2.6% and it was 3.8% and 1.7% in placebo and antibiotic group respectively.

Out of 110 patients a total number of 2(1.8%) 1 in each group had developed secondary hemorrhage. The rate is slightly lower than the published rate of 3-5%.[8] Four studies evaluated for postoperative hemorrhage and reported incidence rates. None reported a significant difference in postoperative bleeding between the antibiotic treated group and untreated group.[3] Cannon reported that the rate of postoperative hemorrhage was same in both groups. Antibiotics did not significantly reduce secondary hemorrhage rates.[7] Ahsan F. et al. suggested that in posttonsillectomy secondary haemorrhage there is limited clinical evidence of infection and the use of antibiotics is not necessarily indicated for the treatment of all posttonsillectomy secondary haemorrhage patients.[5]

Antibiotic group returned to normal diet earlier than Placebo group. Placebo group mean Return to normal diet 4.34(±0.78) days and Antibiotic group mean Return to normal diet 4.05(±0.66) days. P value was 0.03 and that was statistically significant. This result is closer to a meta analysis “Antibiotic for Reduction of Post tonsillectomy Morbidity” done by Collin M. Burkart and David L. Steward. The study showed that on average, the antibiotic treated group return to a normal diet in approximately 3.5 days, whereas the control group returned to the normal diet in approximately 4.5 days. The result of the meta analysis demonstrated a statistically significant earlier return to a normal diet in the antibiotic group by slight more than 1 day (mean difference =-1.22 days; 95% CI=-1.97, -0.48; p=. 001). Another study done by Collin et al. regarding posttonsillectomy morbidity shows that, patients taking antibiotics in the post operative period returned one day earlier to their daily routine activities and to oral intake, presenting a statistically significant difference against untreated patients.[1] Grandis et al.reported antibiotics to facilitate earlier return to normal diet, which just reached statistical significance (P=0.05). On the contrary Telian et al. and Cannon et al. revealed antibiotics not to significantly reduce the number of days required to resume soft or normal diet.[7]

Mean duration of hospital stay Placebo group was 2.57 (±1.22) days and in antibiotic treated

group it was 2.45 (±1.14) days. P value was 0.59 that is statistically not significant.

Discussion:

The results of this study show that postoperative pain in antibiotic treated group significantly reduced from 5thand 7rd postoperative day and onwards respectively than those who received placebo. And the patients who received antibiotic had also early return to normal diet in comparison those who did not receive antibiotic, probably due to earlier decrease of pain and odynophagia. There is no statistically significant difference between the patient groups who received antibiotic and who had not after tonsillectomy in respect of fever, nausea and vomiting, reactionary and secondary haemorrhage and duration of hospital stay

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