EDITORIAL

QUALITY CONTROL IN MEDICAL EDUCATION

Among recent years there has been a raging controversy about the control of quality of the medical graduated we produce here. The quality control has been defined as a process for ensuring proper standard in the production. It means that the products should confirm to the set of quality fixed by a tangible standards.

The assessment of the quality of the product in manufacturing sector is easy but in the field of education relating to humanities and medical science the task is formidable. For this, in education regulatory authorities have been created in form of Universities who develop the curricula, syllabi & conduct elaborate examinations at multiple levels. The students are not only declared pass or fail but are also graded.

In medical science, there is an added regulating authority in the form of Medical Councils which have vast statutory powers not only over quality of medical schools but also the teachers. If there is a doubt about the quality of the doctors produces, the best way is to strengthen these regulatory authorities rather than creating an extra constitutional watchdog. After all too many cooks are known to spoil the broth. But before we censor an existing system for inadequate quality control, we must have an incontrovertible evidence that quality is really poor. An arbitrary poor-quality branding by know all would prove to be a tendentious remark and would unjustifiably debase the system.

There is another way to judge the quality of our medical students. If our students are successfully competing the examinations held in other countries in the form of screening tests or licensing exams, there is hardly any reason to worry. The doctors from here are known to have secure very high percentile in USMLE and at other places. It is certainly not due to a sweet serendipity.

It must also be considered that medical institutions are not only producing doctors but represent an important contributors to the economic health of the country. Nowadays medical entrepreneurship is not looked down on condescendingly.

If there are no firm reasons to believe that quality of medical graduates are poor in this country, there is hardly any reason for railroading the medical schools for reducing seats.

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Malnutrition as a Modifiable Risk Factor of Lower Respiratory Tract Infections Among Under Five Children

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ABSTRACT

Background: Pneumonia is the single largest cause of death in children worldwide. Malnutrition increases the incidence and severity of ALRI and similarly it contributes to malnutrition. By identifying and treating the cases of malnutrition will decrease disease burden. **Objective:** To identify malnutrition as a risk factor of lower respiratory tract infection among children of under five years. **Methods and Materials:** A case control study was conducted at Nepalgunj Medical College, Kohalpur Teaching Hospital, Kohalpur, Nepal from June 2014 to November 2014. All diagnosed case of ALRI as per WHO were selected for case group. The controls were healthy children presented in OPD, pediatric ward and immunization clinic. The predesigned case performa with check list was the tool to identifying risk factor of ALRI. All data were entered in SPSS version 19. Descriptive and analytic statistics were used for analysis of data with level of significance at p value <0.05. **Results:** 107 cases and 107 controls were enrolled with age and sex matched. Male to female ratio was 1.6:1 vs 1.8:1 and the proportion of infants, 70.1% vs 68.3% in cases and controls respectively. Moderate wasting was present on 36.4% (39) of case group and 16.8% (18) of control group and It was significantly associated with ALRI (p=0.003). 10.3% (11) of case group children were moderately stunted while 6.5% (7) of control group. It was not statistical associated with ALRI (p=0.325). **Conclusions:** Wasted children were more prone to suffer from ALRI as compare to stunted children. As it is modifiable risk factor, we should focus on effective community education and public health measures to prevent malnutrition.

Key words: *Acute lower respiratory tract infections, risk factor, malnutrition*

INTRODUCTION

According to WHO, Pneumonia is the single largest cause of death in children worldwide. Every year, it kills an estimated 1.2 million children under the age of five years, accounting for 18% of all deaths of children under five years worldwide[1].More than 99% of all pneumonia deaths occurring in developing countries, and three-quarters take place in just 15 countries. The annual incidence of Pneumonia in developing countries is 10-12 times higher than in a developed country that is 10-20/100. However incidences exceeding 50/100 occur with high prevalence's of Malnutrition and high HIV infection rates in children. More than 95% of all new cases of pneumonia in children, less than 5 years occur in developing countries, due to increased prevalence of under nutrition, which is implicated in 53% of all deaths among children less than 5 years[2]. Acute lower respiratory tract infections are ranked among the first five leading causes of mortality in children in most of the developing countries including Nepal. Mortality due to ALRI was 18% of total under five mortality rates, which were 61 per 1,000 < 5 yrs population. Half of children with symptoms of ARI were taken to a health facility or health provider. Seven percent of children with ARI symptoms received antibiotics. So that Ministry of health and population recognized ALRI as a major public health problem among under five year children[3].

The excess of morbidity and mortality rates from acute lower respiratory tract infections in the developing world indicate the several risk factors could be responsible. In developing countries malnutrition, lack of breast feeding, lack of immunization and overcrowding were reported as the usual risk factors of acute lower respiratory tract infections[4-7]. Nationally 11% of children of under five age were wasted and 3% severely wasted whereas 41% of under five children were stunted and 16% severely stunted[3] and malnutrition increases the incidence and severity of ALRI and similarly it contributes to malnutrition[3,8]. So if we can able to identify and treat the cases of malnutrition, it will not only decrease the ALRI but also contribution on prevention of malnutrition as.

METHOD AND MATERIAL

A case control study was conducted at Nepalgunj Medical College, Kohalpur Teaching Hospital, Kohalpur, Nepal during the period from June 2014 to November 2014 to identify malnutrition as a risk factor of acute lower respiratory tract infection among the children below five years. All diagnosed case of ALRI as per WHO were selected for case group, the duration of illness being less than 30 days[9]. In the control group healthy children who were accompanied with their mother in OPD, in pediatric ward and immunization clinic without respiratory symptoms and no history of ALRI in past 2 weeks were included with age and sex matched on consideration. The convenience non probability sampling

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technique was undertaken and the minimum required sample size was 107 in both case and control group. Informed consent was taken from the mother of both groups and willingness was kept on consideration. All sociodemographic data were collected with face to face interview from mothers by researcher himself. Weight was recorded accurately on an electronic type of weight scale after correcting the scale or any zero error before measurement. Under 2 years old children, the length were recorded by placing the child supine on the infantometer. Standing height was measured by using stadiometer for the children of two years age and above. The predesigned case performa with check list was the tool to identifying modifiable risk factor of ALRI. All data were entered in SPSS version 19 and descriptive and analytic statistics was used for analysis of data with level of significance at p value <0.05.

RESULTS

Mean age of the case group 11.34±10.168 (M±SD) months and control group 11.57±10.270 (M±SD) months. Among them 70.1% (75) were below 12 month of age in case group whereas 68.3% (72) in control group. Male to female ratio was 1.6 to 1 and 1.8 to 1 in case and control group respectively. 42.1% (45) mothers were illiterate in case group whereas 6.5% (7) in control group. Which is statistically significant (p=0.001). 40.2% (43) fathers of case group were unskilled worker and 15%(16) in control group. Which was also statistically significant (p=0.03). In table no. I majority of families (84.1%) were residing in rural areas in case group and 66.1% in control group (p=0.001). 28% mothers of case group were teenager while they were only 13.1% in control group and Children of case group mothers were 1.5 times higher chance of getting ALRI than controls (p=0.005). According to modified Kuppuswamy's scale, socioeconomic status had been classified into five classes (shown in bar diagram). None of the family was there from upper socioeconomic status. 25.2% (27) of case group family were belonging to lower socioeconomic class but none from control group. It was statistically highly significant (p=0.0001).

As per WHO criteria of assessing severity of ALRI (pneumonia), 56% (60) were diagnosed as cases of severe pneumonia, 35% (37) as pneumonia and 9% (10) were very severe pneumonia. Table no. 2 showed moderate wasting was present in 36.4% (39) of case group and 16.8% (18) of control group, according to new WHO growth chart 2007 and moderately wasted children were 2.8 times higher chance of suffering from ALRI than normal children. It was significantly associated with ALRI (p=0.003). Similarly, 10.3% (11) of case group children were moderately stunted while 6.5% (7) of control group. There were not any statistical association between stunting and occurrence of ALRI (p=0.325) but moderately stunted children were 1. 6 time higher chance of getting ALRI than normal children.

Variables	ALRI		Total (%)	Odd ratio (95% CI)	p value
Address	Case (%)	Control (%)			
Rural	90(84.1)	47(43.9)	137(64)	6.758 (3.55-12.86)	0.0001
Urban	17(15.9)	60(66.1)	77(56)		
Maternal age					
<20	30(28)	14(13.1)	44(20.5)	1.50 (1.160-1.954)	0.0005
20 to 28	77(72)	93(86.9)	170(79.5)		

Table No. I Distribution of demographic variables of case and control group

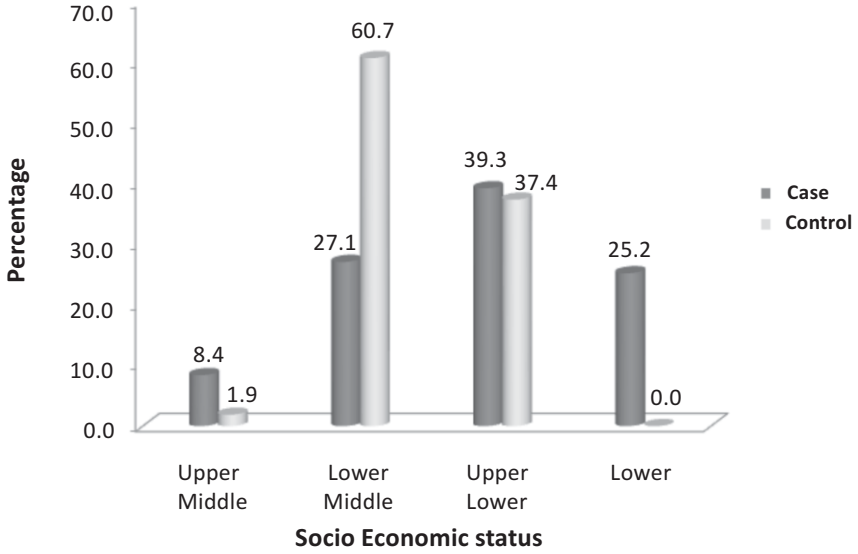

Figure 1: Distribution of socio-economic status in case and control group

Variables	ALRI		Total (%)	Odd ratio (95% CI)	p value
Weight for Height	Case (%)	Control (%)			
Moderately wasted	39 (36.5)	18(16.8)	157(73.3)	2.83(1.423-4.973)	0.003
Normal	68(63.5)	89(83.2)	57(26.7)		
Height for Age					
Moderately stunted	11(10.3)	7(6.5)	196(91.6)	1.6 (0.723-3.146)	0.325
Normal	96(89.7)	100(93.5)	18(8.4)		

Table No. II: Distribution of cases and controls according to nutritional status and its association

DISCUSSION

A total number of 107 cases and 107 controls (age and sex matched) were selected in our study population, where majority of children from cases and controls were infants 70.1% and 68.3% respectively. This finding goes in accordance to other studies reporting 62.5% vs 74.04%[10], 62.2% vs 66.9%[11] and 70.7% vs 67%[12] in cases and controls respectively. It is explained by the fact that various anatomical and physiological risk factors in infants such as they are obligate nose breathers, tongue relatively large, airway narrow, increase metabolic demand and less elasticity of alveoli; associated with incomplete establishment of immunity[13]. Male preponderance was found in both case and control groups (61.7% vs 64.5%) with male to female ratio 1.6:1, 1.8:1.

results were found in different studies conducted in different countriesd[6,10&11]. The possibility of gender bias in seeking medical care may be the cause it. Lower level of education of mother was significantly associated with ALRI and it is similar to other studies. Rural children had six times higher risk of ALRI as compared to urban children (p=0.0001) which was also documented by other researchers from India[10], Bangladesh[14] and Nepal[6]. It might be due to poor access to medical care, low socioeconomic status, low parental education level, poor hygiene, indoor pollution due to cooking fuel and poor knowledge about preventive measures of ALRI in their families. It was observed higher prevalence of ALRI among the children from low socioeconomic class (26.2% vs 8.2%) with its significant association with ALRI (p=0.0001)[15].

Similar was the finding of study conducted in Nepal (38.5% vs 20%) with 2.5 times at higher risk of ALRI[6]. The assessment of malnutrition was done, according to WHO classification of malnutrition. For it weight for height (length) and height (length) for age were taken as criteria of wasting and stunting respectively, labeling as with and without edema. In our study 36.4% children of case group and 16.8% of control group were moderately wasted without edema i.e. malnourished (as wt. for ht. was between -2 to -3 Z score value). Presence of malnutrition (wasting) was significantly associated with ALRI (p=0.001). No significant relationship was established with stunting (10.3% vs 6.3%). Similar was the observation of other researchers[6, 7, 10 & 11]. A study was conducted at Philippines, they reported highest risk of death from ALRI due to malnutrition among those below two years of age[8]. It is well known that malnourished children have defective cell mediated immunity secondary to thymolymphocytic depletion leading to severe gram negative infections and sepsis. They may also have qualitatively abnormal immunoglobins, and impairment of key enzymes involved in bactericidal action of leucocytes, thereby making them all the more prone to infections[16].

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Autologous Serum Skin Test in Chronic Idiopathic Urticaria

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ABSTRACT

Background: Urticaria is a short-lived swelling of skin and mucosa due to plasma leakage by immune and non immune mediated activation and released of mediators from mast cell and basophil. Autoimmune urticaria tends to have a high itch and wheal score than other type of urticaria. Its diagnosis is practically relied upon clinical suspicion and autologous serum skin test. Autologous serum skin test (ASST) is the simple and cost effective test to differentiate autoimmune urticaria from the bulk of chronic urticaria patients. **Objective:** To compare the features of chronic urticaria in patients having positive versus negative autologous serum skin test (ASST). **Materials and methods:** Cross-sectional hospital based study was conducted among 90 chronic urticaria patients (CIU) attending the outpatient dermatology department of Nepalgunj Medical College, Nepalgunj, during one year period. The study was conducted after ethical approval from the institutional committee. The patients were diagnosed on the basis of the appearance of continuous or recurrent hives with or without angioedema for more than 6 weeks. Patients who suffered from either acute urticaria or urticarial vasculitis or physical urticaria or other systemic diseases known to cause urticaria were excluded. Standard tools and techniques were used to prepare autologous serum and injection of the serum and interpretation of the result. The test result was interpreted as positive and negative autologous serum skin test. **Results:** ASST was positive in 42% of the patients and negative in 58% of the patients. The ASST-positive patients had a higher mean urticaria activity score and median duration of wheals in comparison with the ASST-negative patients. Wheals lasted for significantly longer duration in patients with positive ASST. Patients with positive ASST had more frequent attacks which was statistically significant compared to the ASST-negative group. The mean urticaria activity score was significantly higher in the ASST-positive patients than that in the ASST-negative patients. **Conclusions:** . Autologous serum skin test may be a useful screening test for autoimmune urticaria and may be used as a simple and cost-effective test for the classification of chronic urticaria.

Key words: *Autologous serum skin test (ASST), chronic idiopathic urticaria (CIU), Immunosupressive drugs, urticaria activity score (UAS)*

INTRODUCTION

Chronic idiopathic urticaria (CIU) is one of the commonest skin disorder characterized by the recurrent eruption of short-lived(lasting less than 24 hours) wheals accompanied by redness and itching occurring daily or almost daily for at least 6 weeks and where a predominant physical cause has been excluded[1]. CIU is extremely disabling in its severe form and can be difficult to treat. An affected patient often goes from one dermatologist to another for a cure. Mast cell degranulation is the major pathogenesis of CIU. Until recently, all remaining cases were assigned to the category of CIU since no definite cause of CU was known in those cases. This issue was partially resolved in 1993 when Hide et al[2] demonstrated that autoantibodies against the high-affinity IgE receptor, $F_c\varepsilon R_I\alpha$ cause histamine release in a subset of patients with CU. Further subsequent reports showed that 27-61% of CU patients, depending on the method of antibody detection, had these circulating antibodies in their blood of CU patients[3,4,5,6]. The simplest screening method to identify this group of patients having what was termed chronic autoimmune urticaria (CAU), was found to be the autologous serum skin test (ASST)[7]. Diagnosing these patients as autoimmune urticaria becomes important because uses of systemic immunosuppressive drugs are not justified in chronic idiopathic urticaria unless it is diagnosed as autoimmune in origin. Various methods have been used to categorize chronic autoimmune urticaria. The basophil histamine release assay is currently the gold standard for detecting these functional auto antibodies in the serum of patients with chronic urticaria. However, this bioassay is difficult to standardize because it requires fresh basophils from healthy donors, is time-consuming and it remains confined to research centers. Western analysis, enzyme-linked immunosorbent assays (ELISA) and flow cytometry may be useful for screening in the future and they need validation.

Autologous serum skin test (ASST) is the simplest and the best in vivo clinical test for the detection of basophil histamine-releasing activity. The ASST has a sensitivity of 70% and a specificity of 80% for in vitro basophil histamine release when the serum response is at least 1.5 mm greater than the control

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saline skin test at 30 min[7]. Intradermal injection of autologous serum in these patients elicited an immediate-type wheal and flare response indicating the presence of a circulating histamine-releasing factor that is functional auto antibodies that activate mast cells and basophils by cross linking the high-affinity IgE receptor ($F_c\varepsilon R_I\alpha$). About 50% patients of chronic urticaria have functional auto antibodies to $F_c\varepsilon R_I\alpha$ and 9% to the IgE antibody itself[8,9]. Autoimmune urticaria is thus diagnosed in ASST-positive chronic urticaria patients who exhibit functional autoantibodies against IgE and/or its high-affinity receptor FceRI. It is often clinically difficult to distinguish chronic urticaria from autoimmune urticaria. Its diagnosis is practically relied upon clinical suspicion and autologous serum skin test (ASST) which facilitates for assaying functional histamine release from basophils or mast cells. Patient with CAU tends to have a greater number of wheals with a wider distribution, more severe pruritus and more frequent systemic symptoms[10]. Chronic autoimmune urticaria may be associated with other autoimmune diseases like thyroid disease, vitiligo, diabetes mellitus, pernicious anemia and rheumatoid arthritis[11]. It can reasonably be used as a predictive clinical test to diagnose clinically suspected cases of autoimmune urticaria or at least a subgroup of chronic urticaria patients who are more likely to have an endogenous or autoimmune cause for their disease[12]. For the benefit to patients and dermatologists regarding long-term management in terms of need of using supra pharmacological doses of antihistamines or immunomodulators, the study was conducted with an objective to compare the features of chronic urticaria in patients having positive versus negative autologous serum skin test (ASST).

MATERIALS AND METHODS

A cross-sectional hospital based study was conducted among 90 CIU patients attending the outpatient dermatology department of Nepalgunj Medical College, Nepalgunj from March 2013 to February 2014. Approval of the study was obtained from the institutional committee. Patients were enrolled in the study for ASST after taking informed written consent. CIU patients were diagnosed on the basis of the appearance of continuous or recurrent hives with or without angioedema for more than 6 weeks[1]. The study patients were of either sex and more than 15 years of age and who were off antihistamines for 3 days, 7 days for long-acting antihistamines and 2 weeks for doxepin and corticosteroids or immunosuppressive agents for 6 weeks to 3 months as per the procedure[7,12].

Patients having acute urticaria, urticarial vasculitis, physical urticaria (diagnosed on the basis of history/provocation tests) or other systemic diseases known to cause urticaria were excluded. Pregnant and lactating mothers were also excluded. Routine investigations like complete blood count, random blood sugar, urine and stool examination were done to exclude chronic urticaria cases that were not idiopathic. All the patients were investigated for thyroid function test (TFT). The ASST test was not performed over the areas involved by wheals in the last 24 hours. The ASST was considered positive when the average diameter of the autologous serum-induced wheal was >1.5 mm of the saline-induced wheal. Symptoms and signs were graded on the basis of the modified urticaria activity score [Table I][10]. Age, gender, age of onset, duration, frequency of episodes, number and distribution of individual urticarial which was recorded at the time of clinical examination were analyzed in relation to the ASST results. The Chi Square, Fischer's exact tests, Mann-Whitney test were applied. P-value less than 0.05, calculated at the 5% level (95% confidence limit), was considered to be statistically significant.

Pruritus severity score
Absent = 0
Present but not disturbing = 1
Disturbing but not hampering daytime activity or sleep = 2
Hampering daytime activity or sleep = 3
Wheel score (average no. of wheals in 24 h)
Less than 10 wheals = 1
10-50 wheals = 2
>50 wheals = 3
Involving almost the whole body = 4

Table I: **Urticaria activity score**

A numerical value is assigned to signs/symptoms(ignoring the wheals size). Urticaria activity score = Pruritus severity score + Wheel score

Preparation of Autologous serum and controls

Two milliliters of patient's venous blood was collected in a sterile glass tube and allowed to clot for 30 min at room temperature. The serum was then separated by centrifugation at 2000 rpm for 15 min and used immediately for ASST and sterile physiological saline (0.9%) for negative control was used[3,13].

Procedure and Interpretation

Approximately 0.05 ml (equivalent to 2 units on insulin syringe that has 1 ml marked as 40 units) each of autologous serum, and sterile physiological saline was injected by a separate syringe intradermally over volar aspect of the left forearm. Autologous serum was injected proximally and normal saline distally keeping a gap of at least 5 cm between the two injection sites. After 30 minute the wheal formed at each injection site is measured at two perpendicular diameters (d_1 and d_2) and the average of the two is calculated[10,13,14,15].

Positive ASST was the one with serum-induced wheal which had a diameter (average of d_1 and d_2) of ≥1.5 mm as compared to the saline-induced wheal at 30 min. Using this criterion, the sensitivity and specificity of the ASST for detecting autoantibodies is 70 and 80%, respectively, and false positive results in healthy subjects and controls are minimal.

RESULTS

Ninety patients participated in the study. About 31% were in age group of 26-35 years followed by 46-55 years (27.8%). Mean age of the participants was 31.59 ± 13.15 years. Most of the patients were females 63(70%). TFT was abnormal among 6 (6.7%) patients. Autologus serum skin test was positive among 38(42.2%) patients (Table II). With respect to gender, age group and TFT, there was no statistical difference (p> 0.05) between the groups of patients with ASST positive and ASST negative. Gender and age had no effect on the status of ASST. The cases in ASST positive and ASST negative group were comparable with regard to status of TFT (Table III).

Patients with positive ASST had more frequent attacks which was statistically significant as compared to the ASST-negative group (p<0.05). Urticaria activity score (UAS) of ≥ 5 was observed in 35 ASST-positive and in 19 ASST-negative patients. UAS was <5 in 3 ASST-positive and 33 ASST-negative patients. Urticaria activity score was higher in ASST- positive patients than ASST-negative patients which was statistically highly significant (p < 0.001). Patients with higher frequency of attacks and activity score could be important features among patients with ASST-positive. The mean urticaria activity score (6.28 ± 1.7) was also higher in the ASST-positive patients than that (5.28±1.7) in the ASST-negative patients which was statistically highly significant (p<0.001). Wheals lasted for significantly longer duration in patients with positive ASST, the median duration being three hours for ASST-positive as compared to one hour in ASST-negative individuals (p< 0.001).

Median duration of the disease was 10 months and 13 months in ASST positive and ASST-negative groups, respectively but was statistically insignificant. Duration of disease might not have affect on ASST result (Table IV).

Characteristics	No. of patients	Percentage
Gender		
Male	27	30.0
Female	63	70.0
Age Group		
15 - 25 yrs.	16	17.8
26 - 35 yrs.	28	31.1
36 - 45 yrs.	16	17.8
46 -55 yrs.	25	27.8
≥ 56 yrs.	5	5.6
TFT		
Abnormal	6	6.7
Normal	84	93.3
Autologus serum skin test		
Positive	38	42.2
Negative	52	57.8
Mean age (years)	31.59±13.15 Min. 15, Max. 61	

Table II: Distribution of patients according to their background characteristics (n=90)

Characteristics	Autologus serum skin test		p-value
	Positive n1(%)	Negative n2(%)	
Gender			
Male	11 (40.7)	16 (59.3)	>0.05
Female	27 (42.9)	36 (57.1)	
Age groups (yrs)			
15 - 25	5 (31.3)	11 (68.7)	> 0.05
26 - 35	13 (46.4)	15 (53.6)	
36 - 45	6 (37.5)	10 (62.5)	
46 - 55	12 (48.0)	13 (52.0)	
≥ 56	2 (40.0)	3 (60.0)	
TFT			
Abnormal	2 (33.3)	4 (66.7)	> 0.05
Normal	36 (42.9)	48 (57.1)	

Table III: Comparison of background characteristics of patients with chronic urticaria according to the status of autologous serum skin test

Clinical Features	Autologus serum skin test		p-value
	Positive n1(%)	Negative n2(%)	
Frequency of attack			
Daily	26 (51)	25(49)	<0.05
1 - 3 per week	12 (34.3)	23(65.7)	
1 - 3 per month	0 (0)	4 (100)	
Urticaria activity score			
≥5	35 (64.8)	19 (35.2)	< 0.001
<5	3 (8.3)	33 (91.7)	
Mean urticaria activity score	6.28 ± 1.7	5.28 ± 1.7	< 0.001
Duration of disease (months) Median	10	13	> 0.05
Duration of wheels (hours) Median	3	1	< 0.001

Table IV: Comparison of clinical features of patients with chronic urticaria to the status of autologous serum skin test

DISCUSSION

This study had evaluated patients with chronic idiopathic urticaria (CIU) by autologous serum skin testing to compare the clinical features of patients with positive and negative ASST results. ASST positivity among 42% of patients with CIU in this study supported the previous studies showing 27-60% ASST positivity[16-24].

The median duration of disease was 10 and 13 months for ASST-positive and negative patients respectively, which was not statistically significant and was comparable to the previous study done by Sabroe et al[10]. Lesions lasted for significantly longer durations in patients with a positive ASST, median duration being three hours when compared to one hours in ASST-negative individuals (p = 0.001). Patients with a positive ASST had more frequent attacks, which was statistically significant compared to the ASST-negative group (p = 0.05). A study done by Sabroe et al. concluded that patients with autoantibodies in their sera have more severe attacks according to several parameters including frequency, duration of individual episodes and sites involved[10]. This is in concordance with our study, which noted frequent long-lasting episodes in ASST-positive patients.

However, the overall age and sex profile of our patients in both the groups was statistically comparable to that reported by most workers[19-21,23,25].

Statistically significant higher UAS of ≥ 5 in our 65% ASST-positive patients as compared with that in 35% ASST-negative patients which was similar to other studies(p=0.001)[10,16-18]. However, not all studies have shown a significant difference in UAS between the ASST-positive and the ASST- negative groups[21,26], signifying variable UAS presentation among these patients.

Autoimmune diseases like thyroid disease, vitiligo, diabetes mellitus, pernicious anemia and rheumatoid arthritis were reported more commonly in patients with autoimmune urticaria[10,11]. Our study showed no difference in TFT status in ASST-positive and ASST-negative ones.

The relationship between chronic urticaria and thyroid autoimmunity had been studied by Leznoff et al[27] and it has been postulated that thyroid autoimmunity may play a role in the pathogenesis of chronic urticaria and angioedema. However, in contrast with previous studies[27], our study could not show positive relationship between chronic urticaria and thyroid autoimmunity. This is likely to be because an insufficient number of patients were included or because TFT and thyroid autoantibodies were not routinely measured for all patients. Therefore, TFT alone is not enough to rule out thyroid disease and the thyroid antibody test should be carried out to rule out thyroid autoimmunity in CIU patients.

CONCLUSION

Patients with autoimmune and non-autoimmune chronic urticaria have no distinctive diagnostic clinical and histological features[1]. Hence, ASST is the only practicable test available to clinicians to detect autoimmune urticaria. The ASST test can be done by a dermatologist to determine whether chronic idiopathic urticaria is autoimmune in origin. This is especially important from a management viewpoint since immunosuppressive therapies may be tried if conventional approaches of management are unsuccessful.

LIMITATION OF STUDY

- The study was inherently limited by the small sample size and
- There was no any objective evidence of off antihistamine and oral steroids days during ASST test which may give false negative ASST results.

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ORIGINAL ARTICLE

Study in the Quality of Clinical Documentation Practice in Chitwan Medical College Teaching Hospital, Nepal

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ABSTRACT

Background: Primary documentation of a patient is crucial for making effective healthcare decision and improvements in the quality of care. The objective of this study was to assess the quality of current documentation practice in tertiary care hospitals. **Materials and methods:** This was an assessment of medical documentation practice of one year from the period of January 2010 to December 2010 in Chitwan Medical College, Teaching Hospital. Total 184 patients' discharge files were enrolled and reviewed. Documentation was reviewed in its quality such as completeness, Coherent, consistency and Legibility. **Results:** In overall pooled analysis, High omission rate was observed in final diagnosis, results (cure, improved, referral and death), hospital stay, and final case summary. Although, satisfactory performance was observed in complete set of forms (72.2%); Patient consent for treatment &release authorization forms (78.2%) and treatment chart (60.8%), the overall pooled performance in ten components showed50% performance gap. Study demonstrated that documentation and its legibility, coherent and consistency in all departments needs substantial improvements in the institution.

Key words: *Audit, documentation, quality care*

INTRODUCTION

Quality assurance in the institution depends upon the availability of accurate data. In health institution, the documentation of a patient is therefore a fundamental skill that underpins high quality patient care[1]. Previous studies regarding quality assurance showed that the adverse incidence rate is higher in those institutions where there is missing of records[2]. Primary documentation of a patient not only for making rapport but also to produce research in clinical case management, future plan for improvement in quality, upgrading the technology, collective reporting to higher authority and for some other medico legal importance. However it is not always given the priority it deserves.

There are many problems with the documentation systems which are uncovered in most of the health institutions. The problems are like missing the data, incorrect data, and duplication of patient's record and unreadable entries. These poor quality records meant that they could not be used as reliable sources of information for quality improvement efforts. Such an unreliable data should not be used in making decisions in healthcare management. The lack of correct and timely entry data can lead to poor choices in clinical practice, medication errors, inappropriate repeating of tests, unnecessary referrals, and the waste of time and other resources. So, it is imperative that all health professionals including nurses and midwives should understand the significance of the contents of the patient's medical records. They should know the potentiality of these documents which can be used in health care planning and quality health care management. Most important finding in previous study pointed that poor quality of the information present in patient records was associated with higher rates of adverse events, implying that the quality of the present patient information is a predictor of the quality of care[3-5]. Moreover, the communication and information deficit was also observed in previous study especially in areas such as medication reconciliation, pending test results, and adequate follow-up plans[6]. That is why, institution of rigorous measurement, feedback, and multidisciplinary, multimodal quality improvement processes improved the inclusion of data elements in discharge documentation which is required for effective health care system.

Chitwan School of Medical Sciences, Teaching hospitals 360 bedded teaching hospital. The annual admissions rate in the year 2010 were 14356. The numbers of cases admitted in Medicine were 3865(26.9%), Paediatrics 1991(13.8%), Psychiatric 496(3.4%), Emergency 3947(27.4%), Surgery 1662(11.5%), Orthopaedics 769(5.3%), Gynecology and obstetrics 1259(8.7%) and ENT head and neck surgery 367(2.5%) respectively. Institute started using electronic discharge system from the mid of 2010. The electronically stored patients information like blood results, imaging results and discharge summaries are available to view by all authorized parties anywhere in the hospital.

Duty staff of respective departments fills all the allocated forms during the admission. Primary information like identification of

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a patient is filled up by nursing staff in admission form, nursing observation form, vital sign chart and Input and output chart. The detail information about diseases like history, examination findings, investigation report, treatment order, operation notes (in surgery), daily follow up notes and discharge summary are completed by duty doctor (house officer).

Prior to discharging the patient from hospital, a discharge summary (this to be hand written or electronic) is required to be completed by the doctor. Copies of patients' record are kept in medical record department.

This study intended to review the current documentation practice in its three components in Chitwan School of Medical Sciences. The first component was its structure which includes the organizational support for the system: staffing, physical space, forms, Technology and materials and standardization. Second component was its procedure which included methods of documentation, retrieving, filing/coding and third component was the quality of the documentation like its coherence and consistency as well as clarity.

MATERIALS AND METHOD

We have performed a retrospective patient record review study in a random sample of 184 patient documentation file in Chitwan Medical Collage Teaching hospital. From each department, we randomly selected admissions file of those patient who were stayed More than 24 hours in hospital from January 2010 to December 2010. The patient records of the sampled admissions were reviewed by a trained team of 3 medical practitioners with a structured record-review process. In the first stage of the review process, Discharge file of all department (Medicine, Pediatrics, Psychiatric, Emergency medicine, Surgery, Orthopedic, Gynecology and ENT/head & neck surgery) from January 2010 to December 2010 were randomly extracted. Patient record file were obtained from record section.

Files were reviewed by physicians in the second stage of the review process. Based on a standardized procedure according to the indicators and its definition, reviewers determined the presence or absence of documentation. All quantitative and qualitative data were entered and analysed using Microsoft Excel. Proportions of all indicators were calculated and reported.

Guidelines

In this study the measurement of the current documentation practice was performed with respect to the data of ten components and its quality indicators according to its definitions[6,7]. Only three component indicators like discharge summary, legible and coherent and consistency were applied to study patient's files of the emergency department.

Components, Indicators and definition of the Quality of Medical Documentation (Adapted[6-7])

Component	Indicator	Definition
1. Complete set of forms on chart	Number of complete medical records in sample, divided by total sample size	The total number of medical records in the sample with all the forms required at final admission.
2.Complete admission and discharge records	No of completed admission records in the form divided by total sample size	The total no of medical records in the sample that have the admission form completed, including In-patient no, name, age and sex, address, provisional diagnosis, final diagnosis, procedure(if applicable), hospital days, date of admission and discharge, result, final case summary.
3.Complete discharge summary records	No of completed discharge summary records divided by total sample size.	The total no of medical records in the sample that have the discharge summary form completed, including In-patient no, name, age and sex, address, name of consultant, date of admission and discharge, final diagnosis, case summary (history, clinical findings), investigations records, operative procedure and findings (if applicable), histopathology report(if applicable), treatment during hospital stay, condition at the time of discharge, special note, advice on discharge and authorized signature.

Component	Indicator	Definition
4. Patient consent for treatment and release authorization forms	No of medical records in samples with a signature on the authorization forms sample divided by total sample size.	The total no of medical records in the sample that had patient signature / finger print on the authorization forms.
5. Vital sign chart	No of medical records in the sample with complete graphical presentation divided by sample size.	The total no of medical records in the sample with that complete includes graphical presentation and patient identification record.
6. Nurses Observation	No of medical records in the sample with complete intake output chart divided by sample..	The total no of medical records in the sample with complete including Temperature, pulse, respiration, blood pressure, observation record including patient identification.
7. Intake and Output chart	No of medical records in the sample with complete intake output chart divided by samples.	Total no of medical records in the sample with complete including date, time, IV infusion, oral,, urine, aspiration, drainage vomitus and colour.
8. Treatment chart	No of medical records in the sample with complete treatment chart divided by samples.	The total no of medical records in the sample complete treatment chart includes patient identification(name age ward IP no, bed no), date, drugs in block letter, dose, route, doctor signature, discontinuation date.
9. Legible	No of medical records in the sample with legible medical notations with respect to the indication, diagnosis and progress note divided by samples.	The total no of medical records in the sample with complete legible medical notations with respect to the indications diagnosis and progress notes. Legible documentation was defined as writing that can be clearly understood on forms with respect to the name of the patient, inpatient no, diagnosis, ICD coding medical/surgical indications and progress note.
10. Coherent and consistent	No of medical records in the sample that were coherent and consistent in content divided by samples.	The total no of medical records in the sample that contained entries that were coherent and consistent with i.e they coincided with the diagnosis, indication and treatment during admission, discharge and ward follow up according to available protocol and that were in chronological sequence and related to the progress notes.

RESULTS AND OBSERVATIONS

Among 184 samples files from eight departments, three of them were without discharge summary. Three of ten components indicators showed only satisfactory score of the documentation practice. Component Indicators with high score performance were complete set of forms, Patient consent for treatment and release authorization forms and treatment chart. The current performances of these three indicators ranged from 60.8 to 78.2 percent. The seven indicators showed small variation in the performances scores of the departments ranged from 30.4 to 58.1 percent among the eight.

Table I summarizes the performance of eight departments in ten quality indicators. Table II summarizes the performance gap among the eight departments. The performance gaps of the inter departments were ranged from 20 to 90 percent. Overall performance gap was observed 50 percent in ten indicators in eight departments.

Component/Quality Indicators	**Departments and percentage**								
	Med. No. (%)	**Pae. No. (%)**	**Psy. No. (%)**	**Emer. No. (%)**	**Sur. No. (%)**	**Ortho. No. (%)**	**OBG. No. (%)**	**ENT No. (%)**	**Pooled No. (%)**
Sample Size	24	23	24	22	24	22	23	22	184
Complete Set of forms	20 (80)	21 (91)	13 (54)	-	18 (75)	18 (81)	22 (95)	21 (91)	133 (72.2)
Complete record in admission and discharge form	10 (41)	4 (17)	3 (12)	-	12 (52)	8 (36)	17 (73)	19 (86)	73 (39.6)
Complete record in discharge summary	9 (37)	14 (66)	5 (22)	6 (27)	7 (30)	15 (68)	17 (73)	14 (66)	87 (47.2)
Patient consent for treatment and release authorization forms	22 (91)	21 (91)	22 (91)	-	18 (75)	20 (90)	20 (86)	21 (91)	144 (78.2)
Vital sign chart record	14 (63)	21 (91)	8 (34)	-	21 (87)	14 (66)	22 (95)	7 (31)	107 (58.1)
Nurses Observation chart record	6 (25)	15 (65)	13 (59)	-	6 (25)	7 (31)	21 (91)	20 (90)	88 (47.8)
Intake and Output chart record	7 (31)	4 (17)	3 (21)	-	10 (50)	4 (21)	8 (34)	20 (90)	56 (30.4)
Treatment chart record	9 (57)	19 (82)	15 (68)	-	12 (50)	18 (81)	20 (86)	19 (91)	112 (60.8)
Legible (clarity)	10 (41)	7 (30)	4 (16)	4 (18)	7 (29)	7 (29)	7 (29)	12 (54)	58 (31.5)
Coherent and consistency of recording	12 (50)	7 (30.4)	4 (16.6)	6 (27)	8 (33.3)	8 (36.3)	10 (43.4)	8 (36.3)	61 (34.2)
Total	125 (52.0)	133 (57.8)	90 (37.5)	16 (72)	122 (50)	119 (54)	164 (71)	161 (73.1)	930 (50)

Med. = Medicine, Pae. = Pediatrics, Psy. = Psychiatry, Emer. = Emergency,
Sur. = Surgery, Ortho. = Orthopedics, OBG. = Obstetrics & Gynaecology

Table I: Number and Percentage of medical records meeting quality standards

Component/Indicator	Med.	Pae.	Psy.	Sur.	Ortho.	OBG	ENT
Complete admission record	0.6	0.9	0.9	0.5	0.7	0.3	0.2
Complete discharge summary	0.7	0.4	0.4	0.7	0.4	0.3	0.4
Nursing management(Vitals, Nursing Observation, I/O Chart)	0.7	0.5	0.8	0.5	0.7	0.3	0.3
Legible	0.6	0.7	0.9	0.8	0.8	0.8	0.5
Coherent and consistent	0.5	0.7	0.8	0.7	0.6	0.6	0.6

Note: "Performance gap" is defined as the proportion of all records in the samples that do not meet a particular standard. For example performance gap 0.5 indicates 50 percent gap need to be eliminated.

Table II: Performance gap to meet each standard

DISCUSSION

The quality of the recorded information in patient records seems to be a predictor of the quality of care. Better registration of patient information could contribute to better patient outcomes and safer healthcare[8]. Documentation in medical records is poorly designed that is why it is difficult to maintain. This deficiency also obtained in this study. Writing case summary in admission form during the time of discharge is wrongly instructed as there is separate from available for writing discharge summary. It should be indicate that case summary should be written at the time of admission not at the time of discharge.

Deficiencies in discharge summary were commonly found in most of the hospital. A review from American Medical Association, found that important data often were missing from discharge summaries. In the review of 73 studies, the primary diagnosis was omitted a median of 17.5 percent of the time, a list of medications at discharge did not appear in 21% of summaries, and pending test result were not included in 65%. In this study there were similar results as afore mentions findings. So lack of standard documentation was observed in admission and discharge form. High omission rate was observed in final diagnosis, result (cure, improved, referral and death), hospital stay, and final case summary. Missing patient record components and poor records of the available patient information probably reflect different underlying problems in hospital. The first suggesting administrative and process issues is the inability to use of available An electronic discharge summary more easily create hospital discharge summaries but there was no difference in primary care physicians satisfaction[9-10]. The training in electronic format is necessary to crate prompt and accurate documentation in admission and discharge summary.

During admission the presenting symptoms, main clinical findings, investigation finding, treatment protocol/ guideline should be recorded. However, redesigning of the admission form is recommended. Hopefully final corrected form for the admission will prevent the high omission rate. High omission rate was also observed particularly the subjects like blood transfusion record in anemic case, Blood Pressure record for hypertensive case, blood sugar level for diabetic patient at day of discharge. Likewise electrolyte and blood count (platelets) etc. Records of inter departmental consultation, use of standardized medical abbreviations, whether case was admitted from emergency/ OPD, operative findings, Status during hospital admission/stay (any complication observed), time of follow up were frequently omitted in discharge summary. There is relatively high omission rate of the patients discharge condition. Ideally such information allows the sub acute care team to understand the patients health and functional status at the time of hospital discharge, enabling the team to better identify the worrisome about discharged patient. They otherwise do not know well. Lack of accuracy and continuity increases complication rate[11]. In this study, frequent omission was observed in recording passage of stool/urine; correct using of sign, lack off intervention record on the chart like operation, antibiotic, blood transfusion etc.

Compared to the admission and discharge record, quite satisfactory performance rate was observed in complete set of forms (81.7%). Performance score (78.2%) was observed in patient consent for treatment and release authorization forms. The performance score observed in component in quality indicator was complete set of forms (72.2%) followed by treatment chart 60.8 percent. Most physicians report having engaged in questionable hospital chart documentation. This practice is more common among physicians who are younger, working with house staff[12]. As physicians the majority of discharge summaries even though they usually receive little or no trains in the creation of discharge summaries during their medical school. It is possible that differences in formal education or informal discharge summary training during residency accounts for the variation observed here.

CONCLUSION

The structure which includes the organizational support for the system was not impressive. There was inadequate allocation of staff, very congested physical space, poor filing and computer entry system. Technology and materials were used substandard. Substantial improvement is need in the future regarding the methods of documentation, retrieving, filing/ coding. In the process of taking consent the indication of the treatment/operation, minor/major side effects and complications should be discussed before taking signature, however the process of consent could not be assessed in this study. Provision of a room with adequate space should be available near to the ticket counter which provides the advantage to abstract follow up record immediately. The hospital record file for the follow up patient should be reached beforehand in outpatient department during follow up visits. A guideline for the documentation should be produced and implemented to enhance quality documentation.

In only a minority of the quality indicators specified rigorous practice of documentation in Chitwan School of Medical Sciences. Overall results demonstrated that the admission record, legibility of discharge summaries and coherent and consistency of documentation were poorly adhere to most of the standard, however given information play a pivotal communication role in case management /transitions. Even a small frequency of discharge condition information is a concern and may influence patient safety. Standardization itself affects practice patterns substantially. A modification of the documentation system component standards might be instrument in changing CMC discharge summary documentation practice.

Limitation of the study

This study did not look for the implication of poor documentation practice, Complication, re-admission and death as well as implication in cost. The primary limitation of this study relate to its preliminary nature and overall generality. Given that this result are based on a subset of our total sample, including only a very small number of cases. The component definition presented here was set as local standard might not be suitable for the measurement in other institution.

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ORIGINAL ARTICLE

Depression with Somatic Symptoms in Patients Attending Psychiatry OPD of Nepalgunj Medical College

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ABSTRACT:

Background: Depression is the most common mental health problem but its presentation may not be the same all the time. Presentation of depression in the form of somatic symptoms makes it difficult to identify by untrained eyes which needs detailed investigations before labeling them as having a psychiatric problems. **Methods**: This is a descriptive study done in patients attending psychiatry OPD of Nepalgunj Medical College, Kohalpur, for six months from the month of May to October 2014. **Results**: Out of the 240 study subjects, the most common age group is 21-30 years, 90(37.5%), followed by 11-20 years, 50(20.83%). Among the physical symptoms, Generalized weakness 145(29.84%), loss of appetite 106(21.81%), vague pain (joint/abdomen) 84(17.28%), headache 80(16.46%), burning and tingling sensation 71(14.61%). **Conclusions**: Depression is a common psychiatric entity but may present in the form of physical symptoms. The commonest being generalized weakness 145(29.84%), followed by loss of appetite 106(21.81%).

***Keywords**: Depression, ICD, Nepalgunj Medical College, somatic symptoms*

INTRODUCTION

Depression is the most common mental health problem. Major depressive disorder has the highest life time prevalence of 17% of any psychiatric disorders and women being twice as likely to be affected as men[1]. Though there are various typical signs and symptoms in depression, it may commonly disguised in somatic sign and symptoms and this is the reason of difficulty in diagnosis, wrong diagnosis, unnecessary and costly investigations and poor treatment outcome. These patients experience and describe emotional distress in terms of physical symptoms[1].

A high percentage of patients with depression who seek treatment in a primary care setting report only physical symptoms, which can make depression very difficult to diagnose. Physical pain and depression have a deeper biological connection than simple cause and effect; the neurotransmitters that influence both pain and mood are serotonin and norepinephrine. Dysregulation of these transmitters is linked to both depression and pain. In general, the worse the painful physical symptoms, the more severe the depression[2]. As depression can present with other physical comorbid illnesses, ruling out of such possibility is important before labeling such symptoms as somatic symptoms of depression[3,4]. The literatures report that more than fifty percentage (up to two third) of depressive patients present with somatic symptoms including generalized weakness, headache, joint pain, burning and tingling sensations, crawling sensations and vague pain[1]. Somatic symptoms including painful physical symptoms are not only associated with diagnostic difficulty and poor treatment outcome but also poor quality of life of the sufferer[5].

As per the ICD-10 (International Classification of Diseases, 10th edition), typical somatic symptoms (also called biological, mealancholic, vital or endogenomorphic) are anhedonia, lack of emotional reactivity, depression being worse in the morning, waking in the morning two hours prior to the usual time, psychomotor retardation or agitation, marked loss of appetite, significant weight loss, severe loss of libido. Somatic syndrome is considered if four of these symptoms are definitely present[6]. In this article, somatic symptoms are considered for physical symptoms of depression (Not the cognitive or affective) which patient present with and not exclusive of all the biological symptoms. Typically, in depressive episode, individual suffers from depressed mood, loss of interest and enjoyment, and reduced energy leading to increased fatigability and diminished activity. A duration of at least 2 weeks is usually required for diagnosis, but shorter periods may be reasonable if symptoms are unusually severe and of rapid onset[6].

METHODS

This is a descriptive study done in patients attending psychiatry OPD of Nepalgunj Medical College, Kohalpur for six months from the month of May to October 2014. All the new cases of depression who came to OPD were included in the study after

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taking consent for the study and publication of the same. Total 240 participants were included in the study. Patients were diagnosed using ICD-10 (International Classification of Disease, 10th edition) classification of mental and behavioral disorders, clinical description and diagnostic guidelines[6]. Patients who did not want to participate in the study, those having depression with bipolar disorders, depression in schizoaffective disorders, depression with substance dependence and organic depression were excluded from the study group. Patients who needed psychological intervention were sent to the psychologist working in the same hospital.

Age	Gender		Depression as per ICD-10	
	Male	Female	No.	%
≤ 10	2	5	7	2.92
11-20	15	35	50	20.83
21-30	20	70	90	37.5
31-40	10	26	36	15
41-50	12	32	44	18.33
51-60	3	5	8	3.3
>60	1	4	5	2.09
Total	63	177	240	100

Table I. Demographic profile of patients having depressive episodes with their age range (n=240)

Gender	No.	%
Male	63	26.25
Female	177	73.75
Total	240	100

Table II. Frequency with respective percentage of patients with depression (n=240)

Needful laboratory investigations were done from the hospital laboratory.

The basic socio-demographic profile was recorded and the variables were analyzed using SPSS (Statistical Package for Social Studies) software and tabulated in percentage.

RESULT

Out of the 240 study subjects (n=240), the common age group involved in population was 21-30 years, 90 (37.5%); followed by 11-20 years 50 (20.83%), and 41-50 years 44 (18.33 %). Number of female patient was 177 (73.75 %) and male only 63 (26.25 %). The male to female ratio was 0.35.

The commonest somatic symptom in depression is generalized weakness 145 (29.84%) cases, followed by loss of appetite 106 (21.81%), vague pain (joint/abdomen) 84 (17.28%), headache 80 (16.46 %) and burning or tingling sensation 71 (14.61%) patients.

Important findings are given in the respective tables below.

Somatic symptoms	No	%
Generalized weakness	145	29.84
Headache	80	16.46
Burning and tingling	71	14.61
Loss of appetite	106	21.81
Vague pain (Joint/abdomen)	84	17.28
Total	486	100

Table IV. Frequency of somatic symptoms with respective percentage in patients with depression (n=240)

Age (yrs.)	Somatic Symptoms				
	Generalized Weakness	Headache	Burning and tingling	Loss of appetite	Vague pain joint/abd
≤ 10	-	2	-	1	5
11 - 20	28	15	9	18	10
21 - 30	55	32	19	43	17
31 - 40	22	11	13	20	17
41 - 50	27	16	25	19	22
51 - 60	8	3	2	2	8
> 60	5	1	3	3	5
Total	145	80	71	106	84

Table III. Distribution of somatic symptoms in patients with depression (n-240)

DISCUSSION

The most common age range for depression found in our study is 21-30 years that represent 37.5 percent of depression cases. In the gender distribution, our findings represent more females 177 (73.75%) than in males 63 (26.25%). Depression is said to be twice more common in females but our excess female depression finding could be due to nature of our catchment area where males go to abroad or nearby country India for their earning but females stay at home looking after their children so that they come to us when they get problems. Also, the somatic symptoms may also have produced more concern for their general health in those females.

The another similar study done showed more females presented with higher number of somatic symptoms where males presented higher number of psychological symptoms[7]. The most common somatic symptom is generalized weakness 145(29.84%) followed by loss of appetite 106 (21.81%). Vague pain (joint/abdomen) 84(17.28%), headache 80(16.46%) and burning and tingling sensations 71(14.61 %). In one hospital based study done in USA in patients with coronary heart disease, fatigability was the most common somatic symptom (69%) which is also similar to our present finding where generalized weakness is the most common somatic symptom[8]. In children aged <10 years headache and vague pain (Joint/abdomen) is more common than other somatic symptoms .This finding is as per the usual text book description of presentation of depressive symptoms in children[1].

In one study done in children and adolescent mental problems, it was found that functional somatic symptoms were consistently associated with anxiety and depressive symptoms and disorders with likelihood of more number of such diagnosis with increased number of functional somatic symptoms[9]. In another study conducted in Japan, it was found that the prevalence of depression was positively associated ($p < 0.001$) with total number of somatic symptoms[10]. Though we could not compare in our study, it is said that people from Asian countries more somatize mental problems including depression. In one study regarding expression of distress, Chinese out patients reported more somatic symptoms compared with Euro-Canadians who in turn reported more psychological symptoms[11]. Somatic presentation is not only associated with diagnosis of depression but with the prognosis also. In one study regarding recurrence of depression, it was observed that a sustained high level of medically unexplained physical symptoms predicted consecutive depression reoccurrence over 3.5 years[12].

Somatic symptoms often disguise depression that may mislead the clinicians to omit or wrongly diagnose the patients. Understanding somatic features in depression helps in better management of patient and overall health. Selection bias due to hospital based study, unable to randomize, unable to follow up are some of the limitations of the study.

CONCLUSIONS

Depression is a common psychiatric entity with various symptom profiles including somatic symptoms. The most common somatic symptom is generalized weakness followed by loss of appetite, vague pain (joint and abdomen), headache and burning or tingling sensations.

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Demographic Profile and Childhood Morbidity Pattern in Western Nepal

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ABSTRACT

Background: Nepalgunj Medical College, is a tertiary care centre in western Nepal. This part of Nepal is under privileged with high rate of illiteracy and poverty leading to various morbidities including pediatric problems. This study is carried out as there have not been much studies with this regard specially from this part of the country. **Methods**: This is a retrospective study done in patients admitted in pediatric ward of Nepalgunj Medical College, Kohalpur, for six months from June to November 2014. **Results**: Out of 949 patients admitted in Nepalgunj Medical College, Kohalpur, 604 (63.6%) were male and 345(36.4%) were female. Age range 1-5 years had the maximum number of patients 342(36%) of the total hospital admissions. Respiratory tract infections were the most frequent cause of childhood morbidity 266 (28%) followed by central nervous system illness 138 (14.5%) and gastrointestinal system illness 122(12.9%). Mean hospital stay was 4.3 days. **Conclusions**: Respiratory tract infections were the most frequent cause of childhood morbidity 266(28%) followed by central nervous system illness 138(14.5%) and gastrointestinal system illness 122(12.9%).

***Keywords**: Childhood morbidity, Nepalgunj Medical College*

INTRODUCTION

Nepalgunj Medical College, being a tertiary care centre in western Nepal, entertains patients from mid-western and far-western regions of western Nepal. Western Nepal is under privileged with high rate of illiteracy and poverty leading to various morbidities in general and pediatric population is no exception. An understanding of the epidemiological trend in hospital admissions, including morbidity pattern is critical for healthcare planning and appropriate resource allocation. Ninety percent of children in the early 21st century are born into the developing countries.

According to World Health Organization (WHO), 10.5 million children younger than 5 year died in 1999. Of these, 99% lived in developing countries. Worldwide, children younger than 15 years comprises of 28% of total population[1].

Among the pediatric population, under five morbidity and mortality are very high. As per the World Health Organization report 2012, Nepal has neonatal mortality of 24/1000 live birth, infant mortality of 34/1000 live birth and under five mortality is 42/1000 live birth[2]. These indicators are higher than figures from well to do countries and it's a big challenge not only to the government but also to all the medical personals working in child health. This study is carried out as there have not been much studies with this regard specially from western part of the country.

MATERIALS AND METHODS

This is a retrospective study carried out at pediatric ward of Lord Buddha Educational Academy, Nepalgunj Medical College Teaching Hospital, Kohalpur, Banke over a period of 6 months from June to November 2014. Total 949 cases were admitted in the pediatric ward during that period. Patients were admitted from emergency room and pediatric out patient department and were attended and managed by pediatric residents and pediatricians.

The details of each case were taken from patients case records. Name, age, sex, address, ethnicity, date of admission, duration of hospital stay and diagnosis were recorded from the record file. Patients who were referred from emergency department were excluded from the study. The data so collected was subjected to standard statistical analysis.

RESULTS

A total of 949 patients were admitted during the study period out of which 604(63.6%) were male and 345(36.4%) were female as shown in Figure 1.

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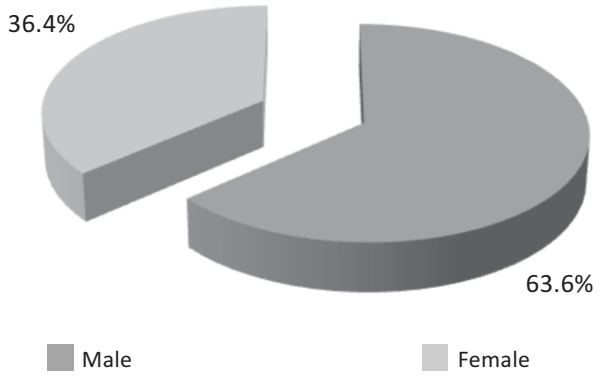

Figure 1. Sex distribution of the patients.

Age (years)	No. of patients	Percentage
1month - 1year	234	24.7
1 - 5	342	36
6 - 10	193	20.3
11-14	180	19
Total	949	100

Table I. Age distribution of the patients

As shown in Table 1, out of 949 patients, age group between 1-5 years had the maximum number of patients i.e, 342(36%) whereas age groups of 11-14 had the least number of patients 180(19%).

Ethnicity	No. of patients	Percentage
Tharu	235	24.8
Brahmnin	165	17.4
Chhetri	259	27.3
Gurung	47	4.9
Others	243	25.6
Total	949	100

Table II. Ethnicity distribution of the patients.

As shown in Table II. Chhetri accounted for the majority of population which consisted of 259 (27.3%) patients.

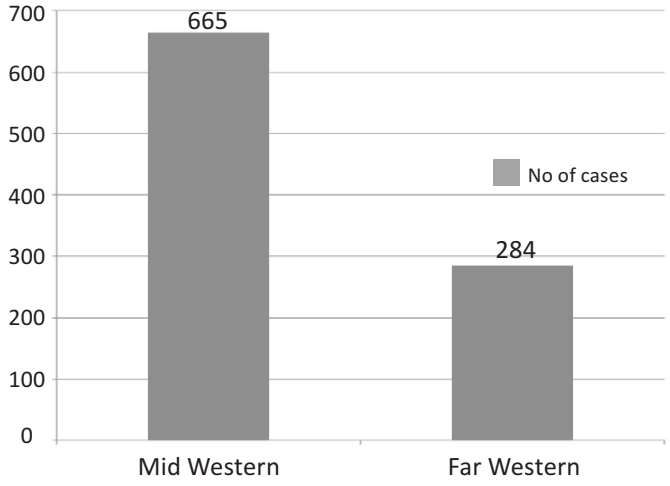

Figure.2 Figure showing geographic distribution of patients.

As shown in Fig. 2 maximum number of patients seeking medical attention came from mid-western region of Nepal accounting for 665(70%) patients. Rest 284(30%) were from the far-western region.

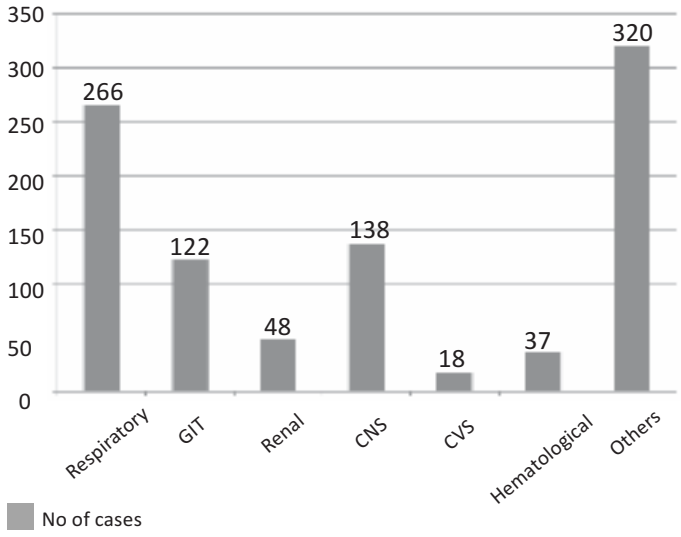

Fig. 3: Showing system wise distribution of disease among patients.

As shown in Figure 3 in the system wise distributions, respiratory tract infections were the most frequent cause of childhood morbidity requiring hospital admission. Total number of patients with respiratory diseases were 266(28%) out of which pneumonia accounted for the most common childhood illness 227(85.3%) patients followed by bronchiolitis 16(6%), tuberculosis 16(6%) and bronchial asthma 7(2.7%) patients.

Gastrointestinal system illness comprised of 122(12.9%) patients out of which diarrheal diseases accounted for majority

of hospital admissions 98(80.3%) followed by viral hepatitis 19 (15.6%) and Kochs abdomen 5(4.1%). Renal system comprised of 48 (5.1%) patients. Patients with nephrotic syndrome were 18(37.5%), post-streptococcal glomerulonephritis 12(25%) and urinary tract infection 18(37.5%). Central nervous system involved 138(14.5%) patients out of which seizure disorder 60 (43.5%) accounted for most admissions. In the seizure disorder most of the patient were of neurocysticercosis followed by tuberculoma. Acute encephalitis syndrome accounted for 33 (23.9%) patients, followed by meningitis 23(16.7%) and febrile convulsion 22(15.9%) patients.

Cardiovascular system related illness represented 18(1.9%) out of which Congenital heart disease comprised of 13(72.2%) and rheumatic heart disease 5(27.8%) patients. There were 37(3.9%) cases of hemolytic anemia with the most frequent diagnosis of thalasseamia, Other cases were with sickle cell anemia, aplastic anemia and G6PD deficiency. Other illness 320 (33.7%) included enteric fever, malaria, kala-azar, poisoining, septicemia, severe protein energy malnutrition, malignancy etc. The minimum number of hospital stay was 1 day and maximum was 38 days with a mean of 4.3 days.

DISCUSSION

Out of 949 patients, 604(63.6%) were male and 345(36.4%) were female. This gender distribution is similar to the study done in Lumbini zonal hospital pediatric inpatients in which out of 977 admitted children, 579(59%) were males and 398(41%) females[3]. In another similar study carried out in Kathmandu at a private medical college, out of 453 patients admitted during the study period, there were 267(59%) male and 186(41%) female children[4].

In another study done in West Indies, out of 1350 admissions there were 570 female and 715 male with $p < 0.0015$. This gender disparity could be due to preference given to the male child over female while seeking treatment as such gender bias is widely prevalent in our catchment area.

Age range of 1-5 years had the maximum number of patients i.e, 342(36%) of the total hospital admissions. This result is similar to the study done in Nepal Medical College where less than five years age group accounted for 180(39.7%) excluding the neonate[4]. Ethnic distribution was as per the distribution of national and regional population distribution given by the central bureau of statistics, government of Nepal in which the most common ethnicity is Chhetri[6]. Our finding consisted of 259 (27.3%) Chhetri patients followed by others 243 (25.6%) and 235 (24.8%) Tharu patients.

Most of patients seeking medical attention came from mid-western region of Nepal accounting for 665 (70%) and 284 (30%) were from the far-western region. This is due to mid-western location and thus more respective catchment area of this hospital.

Among the system-wise distribution of pediatric morbidities, respiratory tract infections were the most frequent cause of childhood morbidity requiring hospital admission representing 266(28%) of patients out of which pneumonia accounted for 227(85.3%), followed by bronchiolitis 16(6%), tuberculosis 16 (6%) and bronchial asthma 7(2.7%) . This is similar to the study done in Lumbini zonal hospital where 309(31.6%) patients comprised of respiratory tract infections including pneumonia, acute bronchiolitis and asthma[3]. This finding of respiratory disease being number one is similar to other studies done in Kathmandu Medical college and Dhulikhel Hospital[7,8].

Gastrointestinal system illness comprised of 122(12.9%) patients out of which diarrheal diseases accounted for majority of hospital admissions 98 (80.3%). This finding is bit lower than findings in another similar study where diarrhoeal diseases contributed 112(24.7%) of pediatric morbidity[4]. Being a tertary care centre, this could be due to lower number patients coming up with acute problems like diarrhoeal disease which is widely treated in health post and sub-health post levels across the country.

Central nervous system involved 138(14.5%) patients with seizure disorder 60(43.5%) accounting for most of the hospital admissions. Among seizure disorder most of the patient had neurocysticercosis and tuberculoma. Acute encephalitis syndrome accounted for 33(23.9%) patients, followed by meningitis 23(16.7%) and febrile convulsion 22(15.9%) patients. This is similar to the study done in Nepal Medical College in which CNS diseases comprised of 43(9%) of which 7(16%) were meningitis and meningoencephalitis and 26(60%) had febrile convulsion[4]. In another study done regarding childhood neurological disorders, it was found that febrile encephalopathies, neurocysticercosis and epilepsy were the most frequent neurological problems in Nepalese children[9].

In our finding, central nervous system problems are more common than gastrointestional illnesses and the reason could be getting more chronic and severe looking illnesses like seizures in such tertary care centre more often than easily treatable and less complicated appearing diarrhoeal diseases.

Cardiovascular system related illness represented 18(1.9%) out of which congenital heart disease comprised of 13(72.2%) and rheumatic heart disease 5(27.8%) patients. This finding is similar to the study done in Lumbini zonal hospital where cardiac patients were 15(1.5%)[3].

There were 37(3.9%) cases of hemolytic anemia with most frequent diagnosis of thalasseamia. Other cases were with sickle cell anemia, aplastic anemia and G6PD deficiency. As thalassemia is more common in Tharu population, more rigorous studies needs to be done with this regards. In one study, though not studied hemolytic anemia separately, childhood anemia in less than 5 years was found to be 46% in children attending to hospital OPD[10].

The hospital stay ranged from 1 day to maximum of 38 days

with a mean of 4.3 days. This finding is comparable with the study done in Lumbini zonal hospital where 85% patients stayed in hospital for 5 days or less[3].

CONCLUSION

Out of 949 patients admitted during the study period, 604(63.6%) were male and 345(36.4%) were female. Age range 1-5 years had the maximum number of patients i.e, 342(36%) of the total hospital admissions.

Respiratory tract infections were the most frequent cause of childhood morbidity 266(28%) followed by central nervous system illness 138(14.5%) and gastrointestinal system illness 122(12.9%). Mean hospital stay was 4.3 days. These findings can be implicated in management of childhood illnesses in this region but more rigorous community studies with large sample size needed to elaborate the exact pediatric morbidity patterns from western Nepal.

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Seasonal Variations in Cataract Surgery Numbers in Mid Western and Far Western Terrain Belts of Nepal

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ABSTRACT

Introduction: In western regions of Nepal many more cataract operations are performed during the winter season than the summer season. This causes problems with resource allocation. The aim of this study was to assess the magnitude of seasonal variation in cataract surgery, explore the causes, and make recommendations to optimize resource utilization. **Methods:** Hospital data of the number of patients undergoing cataract surgery in the years 2011, 2012 and 2013 in 3 hospitals was analyzed by month of surgery. 100 consecutive patients having cataract surgery in the winter season and 100 in the summer season were compared for differences and questioned as to the reasons for choosing cataract surgery at that time. **Results:** Of the 127,718 cataract operations performed over 3 years in the 3 hospitals, 45% were performed in the 3 months February-April and 9% in the 3 months June-August. The mean number performed in March (highest volume month) was more than 7 times higher than that performed in July (lowest month) – 8016 versus 1041 per month. At univariate level nationality, marital status, socioeconomic status, cost per surgery, occupation, age and ethnicity were associated with seasonal variations. Multivariate logistic regression analysis of seasonal uptake showed Nationality/Ethnicity, Socioeconomic status and cost per surgery statistically significant in predicting attendance in high season. **Conclusions:** There is a large seasonal variation in cataract surgery numbers in West Nepal. Factors including patients' nationality cost of surgery and cultural beliefs contribute to the seasonal variation. If these can be addressed then resource allocation and utilization can be improved.

Key words: *Cataract, Nepal, resource utilization, seasonal variation*

INTRODUCTION

The total population of Mid and Far Western Regions (MWR + FWR) of Nepal is approximately 6.5 million people. The prevalence of blindness (Corrected visual acuity in the better eye less than 3/60 or visual fields less than 10 degrees is defined as blindness in Nepal and is a World Health Organization definition as well) in MWR/FWR is 0.23% and 0.41% respectively (Mean 0.32%) giving an estimated 20,000 blind people of which 67% is due to cataract[1].

Eye health care in MWR/FWR is primarily provided by the National Non Governmental Organization (NGO) Nepal Netra Jyoti Sangh (NNJS) with support from International Non Governmental Organizations (INGOs). Many patients from northern India come to Nepal for eye care services[2,3].

Recent data from NNJS indicate that people from India contribute more than 55% of total number of cataract surgeries done in Nepal[4]. The observation that more than half of the annual cataract operations are operated in a four month winter / high season caussing difficulties with planning the allocation of resources, particularly cataract surgical teams[4]. If the demand for cataract surgery could be more equally distributed this could improve the efficiency and possibly the quality of cataract service delivery and better resource utilization in the hospital.

The factors associated with seasonal variation in Nepal have not been studied scientifically. The study thus primarily focused in finding out the magnitude of seasonal variation in cataract surgeries, explore the causes and make recommendations to combat the problem

MATERIALS AND METHODS

Records from three hospitals (Nepalgunj, Fateh Bal and Geta Eye Hospitals), for the years 2011, 2012 and 2013 were analyzed to document the number of cataract operations performed each month.These all study hospitals offer similar prices for the cataract surgery. The base eye hospital (Geta Eye Hospital) and Fateh Bal Eye Hospital are under the roof of NNJS, while Nepalgunj Eye Hospital is a private eye hospital with tertiary level services in Mid Western plain belt. Ethical

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approval for the study was obtained from London School of Hygiene and Tropical Medicine (LSHTM), London, and the Institutional Review Board (IRB) of Nepal Netra Jyoti Sangh, Nepal. All the participants were given written and verbal information about the study, and informed consent was obtained from the participants.

Hundred consecutive patients undergoing surgery for age-related cataract in the high volume winter season and 100 patients in the low / summer season were identified and a standard questionnaire was completed to document various demographic and socio-economic factors. The two groups of patients were also questioned as to the reason for attending in high / winter or low / summer season. Hindus were also kept in ethnic groups with a common agreement that, religiously also they are Hindus. Data was collected, entered in Microsoft excel, and analyzed using Stata version 13. A statistician was consulted when necessary.

RESULTS

A total of 127,718 cataract operations were performed in the 3 hospitals over the period 2011- 2013. The magnitude of seasonal variation was similar in all 3 study hospitals Figure 1). Comparison of the socio-demographic variables in 100 patients questioned in the high/winter season and 100 in the low/summer season is summarized in Tables I and II.

In the high season 92% of patients were from India compared with 69% in the low season; and 79% were from middle to high socio-economic strata compared with 36% in summer. Patients in winter were more likely to be married, male gender and older than those coming in summer. Housewives 16% preferred the winter season where as self employed patients 12 % preferred the summer season occupation wise. Despite being from higher socio-economic strata people attending in the high winter season paid less for cataract surgery than those in low summer season – 99% of patients paid <1500 Nepali Rupees (NRs) in the high season compared with 80% of patients paying 2000NRs or more in the low season.

At univariate level nationality, ethnicity, occupation, cost per surgery, socioeconomic status, marital status, age were associated with seasonal variations (Table I, II).

When Multvariable logistic regression analysis of seasonal uptake was undertaken using the dependent binary variable High Season Attendee and the independent predictor variables significant at the univariate level – Age, Nationality, Ethnicity, Marital Status, Occupation, Socioeconomic Status and Cost of Surgery. Nationality and Ethnicity were combined into one variable due to their interactive properties.

Holding all other factors constant, only Nationality/ethnicity, Socio-Economic Status and Cost of Surgery were statistically significant factors in predicting attendance in high season (Table III). When questioned as to why patients came in the high or low season, 54% of patients attending in the high/winter season said that it was because surgery was safer in winter; while those attending in the low/summer season, 51% said it was because of diminished vision Figure 2).

DISCUSSION

Cataracts are the major cause of blindness and visual impairment in developing countries and contribute to more than 90% of the total disability adjusted life years[5]. There have been various studies focussed on the prevalence of cataract and cataract blinds[1], barriers to uptake cataract surgeries[1], the global burden of cataract[5], the modern methods of cataract surgeries including femtosecond laser cataract surgery specially in developed world[6]. However there have not been significant studies about the seasonal variation in cataract surgery till now specially in developing countries where the prevalence of cataract and cataract blinds is very high[1,4]. Seasonal variation in cataract surgery numbers has remained a significant problem in a poor developing nation like Nepal. Where eye health system runs parallel to the general health system[1,4].

The study clearly demonstrates a consistent seasonal variation in cataract surgery numbers over the last 3 years in 3 independent hospitals. The observation that there is a 7 fold variation in monthly numbers between the busiest and least busy months demonstrates the problem of planning resources for good service provision.

The main differences seen in the high/winter season and low/summer season patients was Indian nationality, higher socio-economic strata and need to pay less for surgery in the high/winter season. Patients attending in high season were significantly far less likely to be Nepali (of any ethnic denomination) than Indian Hindu (OR=0.004, 95% CI=0.00-0.9, p=0.00). Patients were also less likely to be Indian Brahmin or Indian Muslim than Indian Hindu, but this was not significant (Table III).

Patients in the high winter season were seven times more likely to be middle or high income than low income (OR=7.3, 95%CI=1.3-41.5, p=0.03). Despite the higher proportion of middle or high income patients in winter, 99% of surgeries in high season were conducted either free or subsidized compared with 20% of those in low season, leading to an extremely low odds ratio of paying in full in high season compared with low season (OR=0.0002, 95%CI=0.0-0.004, p=0.00). The overall model was statistically significant and explained 84% of the variability by season (McFadden's R2=0.84, p=0.00) (Table 3).

The main reason for attendance in the low/summer season was diminished vision (51%); 61% of these patients were from lower socioeconomic strata and 16% of the summer study

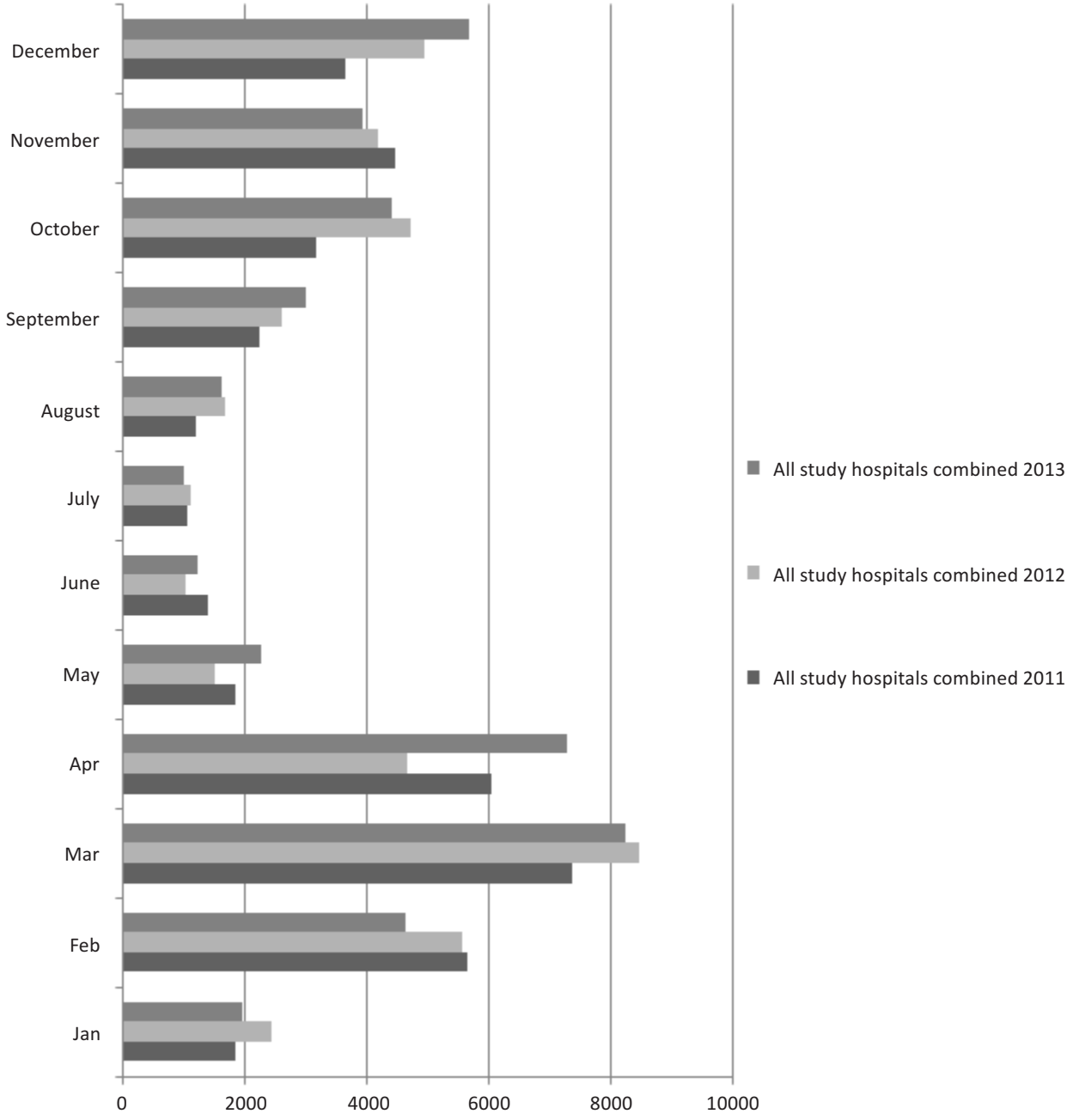


Figure 1: Cataract operations by year and month in 3 Nepali hospitals, 2011-2013.

sample thought the cost per surgery during the summer season is cheaper. However interesting fact which came out from the 200 study subjects of both the seasons was; 99% of the patients in the winter summer season sample were operated in cheaper prices either subsidized or free of cost.

Caution is required in analyzing the data as the 100 patients questioned in summer and winter may not be representative of all patients coming in the high and low seasons, however the study has revealed some interesting information which can be tested to see if people can be persuaded to come in the low / summer season rather that the high / winter season.

Variable	High winter season (100 subjects)	Low summer season (100 subjects)	p value
Gender			
Male	56	43	0.089
Female	44	57	Fisher exact test
Age in years			
Median	60	60	0.0003
Interquartile range	60-65	50-65	Wilcoxon rank-sum
Nationality			
Nepali	8	31	<0.001
Indian	92	69	Fisher exact test
Ethnicity			
Brahmin	9	43	
Tharu	2	19	
Chhetri	17	3	
Magar	0	1	<0.001
Muslim	17	7	Fisher exact test
Vaishya	7	16	
Thakuri	6	1	
Hindu	42	10	
Marital Status			
Married	99	78	<0.001
Widowed	0	21	Fisher exact test
Never married	1	1	
Occupation			
Agriculture	73	74	
Government job	2	4	
Housewife	16	6	0.005
Business	7	3	Fisher exact test
Priest	0	1	
Self employed	2	12	
Socioeconomic status			
Below poverty line	0	20	
Low income	21	41	<0.001
Middle income	77	36	Fisher exact test
High income	2	0	
Education			
No education	78	78	
Primary level	6	8	0.79
Secondary level	9	10	Fisher exact test
College level+	7	4	
Residence			
Remote rural	2	0	
Rural	82	89	0.41
Semi urban	4	3	Fisher exact test
Urban	12	8	

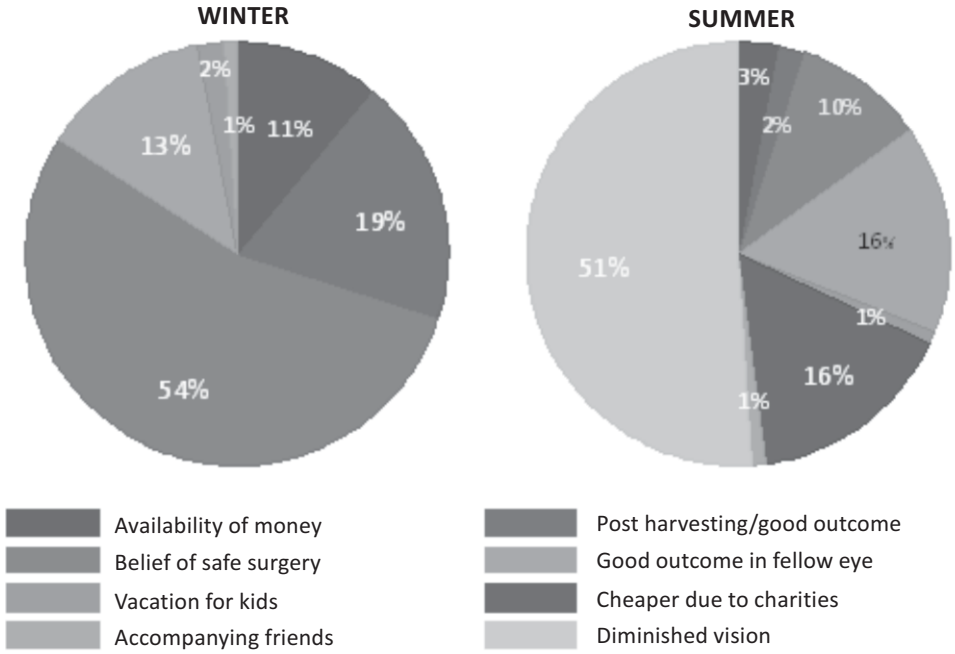
Table I: Comparison of socio-demographic variables in people having cataract surgery in the high/winter and low/summer seasons in 3 Nepali hospitals in 2014

Type of Surgery			
SICS	100	95	
Phacoemulsification	0	4	0.059
Other		1	Fisher exact test
Post operative visual acuity (VA)			
Good	60	65	
Borderline	37	28	0.64
Poor	3	7	Wilcoxon rank-sum
Cost per surgery			
Free of cost	1	20	
<1500 NRS	98	0	
1600 – 2000 NRS	1	0	<0.001
2100 – 3500 NRS	0	75	Wilcoxon rank-sum
5000 – 6500 NRS	0	4	
Other	0	1	
Health Insurance			
Yes	0	1	0.5
No	100	99	Fisher exact test

Table II: Comparison of variables related to the operation of people having cataract surgery in the high / winter and low / summer seasons in 3 Nepali hospitals in 2014

Multivariable Logistic Regression of Predictors of High Season Attendance				
	Low Season Attendees (n=100)	**High Season Attendees (n=100)**	**Odds Ratio (95% CI)**	**p>z**
Age Group				
<65	74%	60%	Baseline	-
>65	26%	40%	1.49 (0.3-8.2)	0.6
Nationality/Ethinicity				
Indian Hindu	9%	37%	Baseline	-
Indian Brahmin	34%	9%	0.26 (0.004-15.4)	0.5
Indian Muslim	7%	17%	0.85 (0.008-88.4)	0.9
Indian Other	19%	29%	0.34 (0.008-14.2)	0.6
Nepalese	31%	8%	0.004 (0.0002-0.1)	0.00
Socioeconomic Status				
Below poverty line or low income	61%	21%	Baseline	-
Middle or High Income	39%	79%	7.3 (0.03-41.5)	0.03
Occupation				
Agriculture	74%	73%	0.2 (0.004-11.4)	0.4
Housewife	6%	16%	Baseline	-
Other	20%	11%	0.2 (0.001-26.0)	0.5
Cost				
Free or Subsidized	20%	99%	Baseline	-
Paid in full	80%	1%	0.0002 (0.0000-0.004)	0.00
Marital Status				
Married	78%	99%	Baseline	-
Never married or widowed	22%	1%	0.2 (0.002-9.7)	0.4

Table III: Multivariable Logistic Regression of Predictors of High Season Attendance



Graphs by season

Figure 2 clearly showing belief for surgery was the main reason for patient attendance during winter, while in summer diminished vision was the main reason for the patient for attending the hospitals.

CONCLUSIONS/RECOMMENDATIONS

It is recommended that the cost of surgery in high/winter be increased or at least equal to the summer cost of the surgery. The free hospital based camps or subsidized surgeries should be encouraged to be done in the summer season more; as the study sample finding could conclude that; the cost per surgery during the winter season is currently lower than the summer season probably due to more charities and funding coming in the winter season.

Most people coming in the winter season are from middle to high socio-economic strata. An increase in price in the winter season or focusing more on subsidized or free surgery during the summer season should not be a barrier to access for cataract surgery but should encourage patients in some shift in choice of seasons. Also consideration should be given to only operating on first eyes in the high/winter season and asking people who want operation on their second eye to come in summer.

As with any policy and behavior change it will be important to inform both providers and patients of why current policy and practice is being changed.

ACKNOWLEDGEMENTS

We would like to acknowledge Nepal Netra Jyoti Sangh (NNJS), Nepal and London School of Hygiene and Tropical Medicine, London, United Kingdom for providing an ethical approval letter to carry out the study. We would like to acknowledge all the patients and study eye hospitals for their kind cooperation. We would like to acknowledge Dr. Catey Bunce and Dr. Islay Mactaggart for the statistical analysis. In the mean time, we would like to acknowledge Dr. Bidya Pant and Dr. Suresh Pant, Geta Eye Hospital for providing information and giving correct data from the hospital.

Finally, we would like to acknowledge Professor Clare Gilbert for her invaluable suggestions.

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Management of the Pre Pubertal Girls with Labial Adhesions

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ABSTRACT:

Back ground: Pre pubertal labial adhesion is an important pediatric gynecological problem. Parents panic about this condition as absent vagina, which is rather very easy to handle in a very simple, rapid, surgical management. **Objective**: the purpose of this study was to evaluate the efficacy of surgical treatment on prepubertal girls with labial adhesions. **Methods**: A period of 3 years from May 2011 to May 2014 was taken to conduct a study about this condition on prepubertal girls. The place of study was Nepalgunj Medical College, Kohalpur, Banke, Nepal. All patients underwent either outpatient surgical treatment or in operation theatre under short anesthesia, those who were either frightened or non cooperative. They were placed in gynecological (dorsal) position. A thin stainless steel lubricated probe or 1-2 mm. size, Hegar dilator was used to separate the labia minora by firm pressure. **Result:** All patients were successfully treated and at present they are being followed for recurrence. **Conclusion:** This benign disorder can be treated by any gynecologist as an office procedure.

Key words: *Labial adhesion, labial agglutination, pre pubertal girls*

INTRODUCTION

prepubertal labial adhesion is an important pediatric gynaecological problem. This is often mistaken with congenital atresia of vagina[1]. Labial agglutination is a condition leading to adhesion of labia minora in the midline. Prior to adhesion there is denudation and thinning of labia[2]. The agglutinations usually begins posteriorly and extends upwards towards the clitoris. Labial adhesion occurs in one to thirty eight percent of female children aged from 13 months to 6 years[3]. Labial agglutination results in a partial or complete adhesion of labia minora. the labia are normally covered with this non estrogenic epithelium. They have been exposed to inflammation and subjected to maceration commonly secondary to vulvo vaginitis

The denuded surface then exude a fibrinous, serosal product causing the labia to adhere or stick to each other. Superficial epithelialisation bridges the adhesions producing an apparent mid line raphe. This process commences at the fourchette and progresses ventrally to varying degree. Therefore the appearance of the raphe is a characteristics livid line extending vertically down the centre of the membranes distinguish agglutination from the less commonly encountered imperforate hymen or vaginal atresia. In doing so it will favor persistence of vaginitis and rarely can cause obstruction of the urethra. The adhesive process with occasionally commence near the clitoris forming so called prepucial adhesion.

MATERIALS AND METHODS

The period of study was between May 2008 to May 2012. All prepubertal girls coming to gynecological outpatient department with the complaint of labial adhesions were included in this study. All patients underwent either outpatient surgical treatment or in operation theatre under short anesthesia who were either frightened or non cooperative. A lubricate stainless steel probe or 2 mm size Hegar dilator was used to separate labia minora with firm pressure and Clotrimazole vaginal cream was applied .

RESULTS

All the cases, adhesions were separated by quick firm pressure with lubricated probe. Short IM anesthesia (ketamin) was used in such situation where the child was non cooperative. We have tried to separate the labia minora without anesthesia by lubricating the probe or Hegar dilator (1-2 mm) with xylocaine jelly without much difficulty.

DISCUSSION

Labial adhesion is a benign genital disorder in girls. Labial fusion may be congenitally acquired, some times happens due to poor hygiene. In this part of the world poor hygiene and cold climate is one of the common cause. The diagnosis can be established by examining the genitalia with a probe and with assistance of the concerned parent (mother). In the circumstance where there is extensive vulvar inflammation the labia majora, it may exhibit certain degree of agglutination. Rectal examination confirms the presence of a normal infantile uterus.

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SN. **Case**	**Year/Month**	**Age of child**	**Socioeconomic Status**	**Treatment**	**Type of Anaesthesia**
1. SS	2008 May	5 year 6 months	Middle	Adhesion was separated by lubricated probe with with quick firm pressure	Ketalar IM
2. KY	2008 Sept.	5 years 3 months	Middle	As above (as SN 1)	Ketalar IM
3. CS	2008 Dec.	4 years 2 months	Middle	As above (as SN 1)	Ketalar IM
4. AA	2009 Sept.	3 years 2 months	Low	Lubricated probe with xylocaine	Ketalar IM
5. VB	2009 Dec.	3 years 6 months	Low	As above (as SN 4)	Ketalar IM
6. LK	2010 Sept.	4 years 1 months	Low	Firm pressure by lubricated probe with xylocaine	Ketalar IM
7. UD	2011 Nov.	4 years 3 months	Low	Same as SN 6	Ketalar IM
8. HH	2012 Jan.	3 years 9 months	Low	Same as SN 6	Not necessary
9. NA	2012 Feb.	2years 4 months	Middle	Same as SN 6	Not necessary
10. US	2012 May	3 years 6 months	Low	Same as SN 6	Not necessary

Table I : **Showing the patient profile and the type of treatment was offered**

SN. Case	**3 months follow up**	**6 months follow up**	**1 year months follow up**
1. SS	No recurrence	No recurrence	Did not come
2. KY	No recurrence	No recurrence	No recurrence
3. CS	No recurrence	No recurrence	Lost to follow up
4. AA	Recurrence + Procedure repeated	Lost to follow up	
5. VB	No recurrence	No recurrence	No recurrence
6. LK	No recurrence	Lost to follow up	Lost to follow up
7. UD	No recurrence	No recurrence	Lost to follow up
8. HH	Recurrence Procedure repeated	No recurrence	No recurrence
9. NA	No recurrence	No recurrence	No recurrence
10. US	No recurrence	Pending	

Table II : S**howing result of follow up**

	N	**Range**	**Minimum**	**Maximum**	**Mean**		**Std. Dev.**	**Variance**
	Statistics	**Statistics**	**Statistics**	**Statistics**	**Statistics**	**Std. Error**	**Statistics**	**Statistics**
Age of the subjects	10	3.20	2.40	5.60	4.0200	0.29657	0.93785	0.880
Valid N (Listwise)	10							

Table III: Statistical analysis of the result

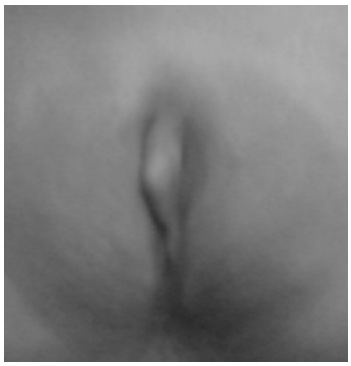

Figure 1: Showing typical labial adhesion with mid line raphe

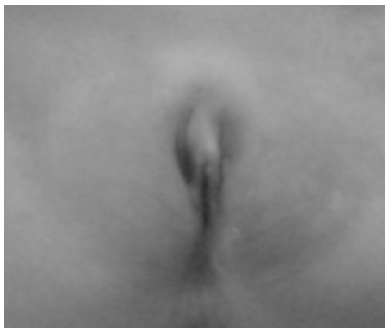

Figure 2: Showing labia minora after separation by lubricated probe

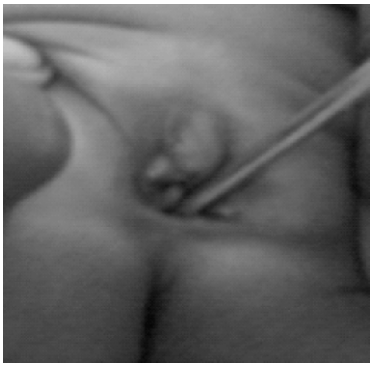

Figure 3: Showing the probe in situ after separation

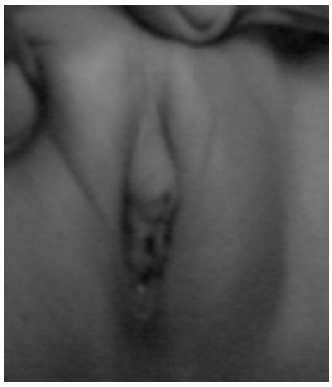

Figure 4: Follow up after 3 months

Labial agglutination should not be confused with labial fusion which is due to intra uterine, congenital or chronic, post nasal inflammation of vulva. In case of fusion simple incision has to be given but one should not confuse it with the virilised external genitalia. The gynecologist should be aware of the situation that labial agglutination is a self limiting condition which usually disappears at puberty when estrogen level in the blood rise. Agglutination encourages pocketing of urine irritation and infection. Labial adhesion may be treated as follows. Lubricated probe is inserted into the anterior opening through which the child passes urine and a quick firm pressure anteriorly readily separates the labia. Estrogen cream or petroleum jelly may be applied which would cornify the epithelium[4]. Repeated separation of labia may be required.

In a study of Gaumden DA et al 2008, 4 girls underwent surgical section and 20 girls received estrogen cream. Mean age was 22 months and 7 cases were five years of age[5]. Mayoglou et al 2009 treated 151 prepubertal girl mean age of 3 years (range between 0.25 -8.75 years) diagnosed to be labial adhesion with topical estrogen and betamethsone therapy was given[6]. Patients treated primarily with topical conjugated estrogen as long as 2.2 months[6]. Side effects of oestrogen include breast budding vaginal bleeding. Patients with labial agglutination frequently may encounter children for whom medical treatment has failed. Thick adhesion require manual separation, bacon et al. 2002[7]. Estrogen treatment has been tried with success with recurrent labial agglutination, Kumetz et al 2006[8]. Gaumdens DA et al. 2008 have used curved Halsted mosquito forceps to separate the adhesions .

The case treated by the authors are described as follows. None of them received topical estrogen cream. In this series we have tried surgical separation of the labia with no. 2 Hegars dilator (2 mm)and application of vaginal cream (antifungal, antibiotic and with steroid) for 4 weeks. The mean age of the subjects was 4.02 years with a standard deviation of 0.93 and range 3.2 to 2.4. The follow up were carried out for 12 months from the date of procedure .

All parents followed up regularly with their kids on first visit after 3 months. Out of 10 children 2 were found to have recurrent adhesions and the procedure was repeated. On second visit after 6 months from the primary procedure one child with repeat procedure did not show up and one without recurrence at first visit did not come up. On 3rd visit after completion of 1 year 50 % patients reported without any recurrence and rest could not report to us despite repeated reminder over telephone (poor compliance).

CONCLUSION

This benign disorder can be treated by any physician, gynaecologist provided they are aware of this condition. It is fairly simple to insert a lubricated probe and put quick pressure

to separate adhesions. The psychological impact of the patient and her parent and necessary speed suggests that surgical treatment is the method of choice. Estrogen cream was not necessary in our series. Although larger sample size and long term follow up is needed to further confirm our inference.

ACKNOWLEDGMENT

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Comparison of Propofol-Ketamine Combination with Propofol-Butorphanol Combination for Total Intravenous Anaesthesia on Short Surgical Procedures

Regmi NK[1], Khatri S[2], Datta PK[3]

ABSTRACT

Objectives: The objective of this study was to compare propofol-ketamine combination with propofol-butorphanol combination for short surgical procedures in terms of hemodynamic and respiratory stability, postoperative sedation, postoperative nausea and vomiting and effect of abolishing pain on injection with propofol. **Methods**: This was a randomized double blinded study conducted in 60 patients belonging to ASA I &II, aged between 16 - 60 years. Patients were divided into two groups: Group-B: Propofol-Butorphanol combination (n=30) and Group-K: Propofol-Ketamine combination (n=30). The baseline values for the heart rate, mean arterial pressure and SPO_2 recorded and every 5 minutes after induction of anesthesia. **Results**: In Butorphanol group MAP at 5, 10, 15, 20, 25 and 30 minutes after induction was significantly lesser but heart rate at 10, 15, 20, 25 and30 minutes after induction was significantly greater than in the Ketamine group with the p value of < 0.05. From 20-30 minutes post induction, SPO_2 in Butorphanol group was significantly less than in the Ketamine group with the p value of < 0.05. Pain after injection of propofol was significantly greater in Ketamine group with the p value of 0.008. There was no statistically significant sedation and post operative nausea and vomiting among the groups. **Conclusion**: Propofol-Ketamine combination provided better hemodynamic and respiratory stability than Propofol-Butorpanol combination however pain on injection with propofol was greater in Propofol-ketamine combination.

***Key words**: Hemodynamic stability, propofol-butorphanol, propofol-ketamine, respiratory stability, sedation,total Intravenous anaesthesia*

INTRODUCTION

Total intravenous anaesthesia (TIVA) is a technique in which induction and maintenance of anaesthesia is achieved with intravenous drug alone; avoiding volatile agents. In this process the patient either breaths spontaneously or are artificially ventilated with oxygen. Total intravenous anaesthesia overcomes some of the disadvantages of traditional inhalation anesthesia. Speedy and complete recovery with decreased post operative nausea and vomiting occurs with TIVA thus is suitable for day care surgeries and early ambulation and also reduces the cost of hospital stay. It avoids risk of malignant hyperthermia syndrome and environmental hazards unlike inhalational agents[1,2].

TIVA has been attempted since 1934 but its use was hampered by cumulative effect of longer acting drugs, inadequate methods of administration like with intermittent bolus administration, leading to peaks and unstable anaesthetic conditions and fear of intraoperative awareness. But with invention of newer induction agents, opoids and amnestic agents having shorter half life and advents of infusion pumps, syringe pumps and target controlled infusions these problems have been declined. Thus TIVA is gaining popularity day by day[3].

Propofol a GABA modulator is a newer intravenous anaesthetic agent, having favourable pharmacokinetic profile. It has a high clearance rate and rapid decline in blood concentration, making it eminently suitable for infusion. When propofol infusion is discontinued there is rapid recovery from anaesthetic state. Propofol has emerged as a gold-standard for TIVA[4,5] for short surgical interventions and day care surgery but its main shortcoming is lack of analgesia, therefore it has to be combined with an analgesic[6].

Pain relief forms an important constituent of balanced anaesthesia. Ketamine and opoids like butorphanol are the popular analgesics in this context. Ketamine a phencyclidine derivative is N-methyl-D-aspartate receptor antagonist. It produces “dissociative anesthesia”. Of the nonvolatile agents, ketamine may be the closest to being a "complete" anesthetic as it induces analgesia, amnesia, and unconsciousness[7]. Butorphanol is a agonist-antagonist opoid that resemble pentazocine. The chief advantages of this agent are its potent analgesia, low toxicity and very low potential for abuse[8,9].

In this study we will compare two drug regimens, i.e. propofol-ketamine and propofol-butorphanol for TIVA technique in patients undergoing short surgical procedures.

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MATERIAL AND METHODS

This was a comparative prospective study conducted from January 2014 to October 2014 in the Department of Anesthesiology, Nepalgunj Medical College Teaching Hospital, Kohalpur in 60 patient undergoing elective short surgical procedure (less than 1 hr.) under total intravenous anaesthesia. Inclusion criteria were patient of either sex, Patient belonging to ASA grade I and grade II, Age between 16-60 years, Patient planned for elective surgery undergoing various short surgical procedures. Exclusion criteria were patient belonging to ASA III and ASA IV, patient with anticipated difficult intubation and difficult mask ventilation, Patient with comorbid medical conditions, history of drug hypersensitivity and unwilling patients.

All patients were admitted to the hospital at least a day before surgery and went a thorough pre-anaesthetic check up. Once shifted to operation theatre routine monitoring was done in all patients and were premedicated with midazolam 2 mg. and glycopyrolate 0.2 mg intravenously. These patients were randomly assigned to one of the two groups in a double blind manner for induction viz; Group B: Inj. Butorphanol 20µgm/kg + Inj. Propofol 1.5mg/kg Group K: Inj. ketamine 1 mg/kg + Inj. Propofol 1.5mg/kg.

Pain on injection with propofol was noted after injecting the propofol in the form of vocal response, facial grimace, arm withdrawal or tears on eye suggesting pain. All the hemodynamics parameter BP, PR, SPO_2 were noted again and then after each 5 minutes of interval till 30 minutes. Anaesthesia was maintained with propofol in the dose of 9mg/kg/hr via syringe pump infusion till the end of surgical procedure and spontaneous respiration was maintained with 100% oxygen via facemask and bain circuit assistance when needed. Incidence of hypotension / hypertension, changes in electrocardiogram and other complications during operation were noted and appropriate action was taken. Sedation was assessed in postoperative period using Modified Ramsay sedation score. Incidence of postoperative nausea and vomiting (PONV) was noted and treated with ondensetron 4-8 mg when needed.

STATISTICAL ANALYSIS

Paired sample t- test was used to compare the means between the two groups and p-value less than 0.05 was considered significant.

RESULTS

Demographic profiles and ASA grading of the patients scheduled for study were comparable.

Mean BP	Propofol Butorphanol		Propofol Ketamine		p value	Inference
	Mean	SD	Mean	SD		
Baseline	90.03	6.52	87.83	8.51	0.268	NS
Premedication	89.36	7.78	89.53	9.43	0.947	NS
Induction	85.63	7.17	91.10	5.95	0.008	S
5 min	83.63	7.97	89.90	6.14	0.002	S
10 min	82.86	8.21	88.30	6.77	0.017	S
15 min	81.36	7.69	86.60	6.42	0.018	S
20 min	80.03	7.18	85.33	6.13	0.011	S
25 min	78.70	6.70	84.30	5.83	0.004	S
30 min	78.03	7.22	83.53	5.61	0.005	S

Table I: Intergroup comparison of changes in Mean Arterial Pressure (MAP)

SD: Standard Deviation NS: Not significant S: Significant

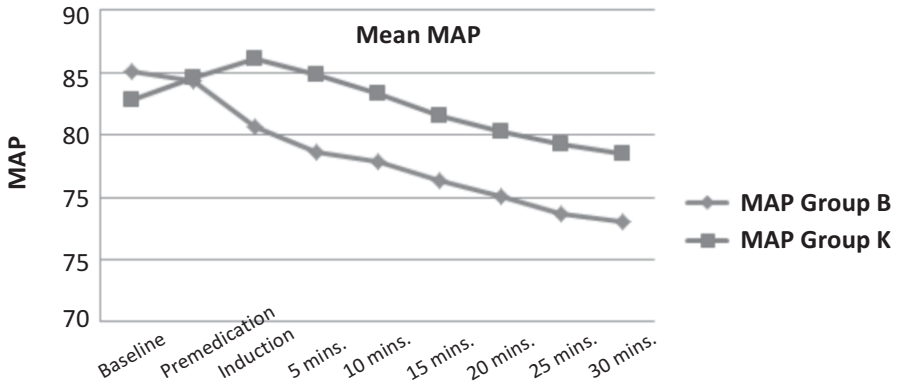

Figure 1: Intergroup comparision of changes in Mean Arterial Pressure

Heart Rate	Group B		Group K		p value	Inference
	Mean	SD	Mean	SD		
Baseline	69.26	8.83	67.70	6.12	0.380	NS
Premedication	75.63	9.66	73.33	7.61	0.282	NS
Induction	78.86	12.62	76.50	9.21	0.363	NS
5 min	80.63	13.71	75.83	9.12	0.062	NS
10 min	82.16	12.50	74.73	8.77	0.003	S
15 min	80.26	11.37	73.26	8.68	0.001	S
20 min	80.93	11.01	72.50	8.58	0.001	S
25 min	79.13	11.56	71.96	7.21	0.002	S
30 min	78.46	10.52	70.73	6.83	0.001	S

Table II: Intergroup comparison of Heart Rate

SD: Standard Deviation NS: Not significant S: Significant

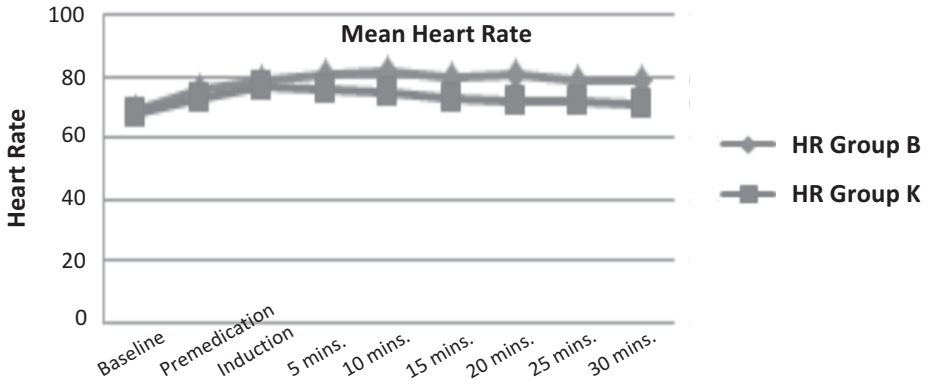

Figure 2: Intergroup comparision of changes in Heart Rate

SPO2	Group B		Group K		p value	Inference
	Mean	SD	Mean	SD		
Baseline	99.76	0.51	99.56	0.56	0.161	NS
Premedication	99.93	0.36	99.86	0.34	0.489	NS
Induction	99.50	0.86	99.86	0.34	0.032	S
5 min	99.56	0.85	99.86	0.34	0.071	NS
10 min	99.56	0.72	99.83	0.37	0.088	NS
15 min	99.56	0.73	99.83	0.37	0.034	S
20 min	99.53	0.81	99.90	0.30	0.032	S
25 min	99.43	0.97	99.90	0.30	0.020	S
30 min	99.53	0.81	99.93	0.25	0.012	S

Table III: Inter group comparison of SPO2

SD: Standard Deviation NS: Not significant S: Significant

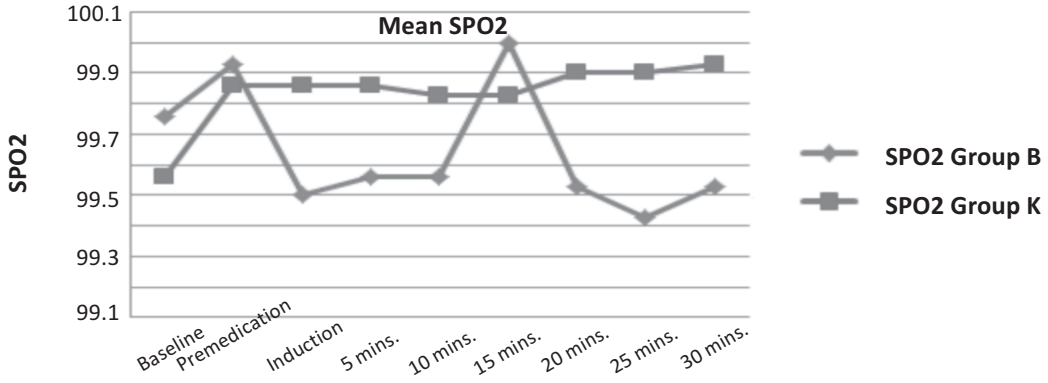

Figure 3: Intergroup comparision of changes in SPO2

POI	Group B		Group K		Total		p value	Inference
	N	%	N	%	N	%		
Absent	23	76.7%	13	43.3%	36	60%	0.008	Significant
Present	7	23.3%	17	56.7%	24	40%		
Total	30	100%	30	100	60	100%		

Table IV: Intergroup comparison of pain on injection with Propofol

POI - Pain On Injection

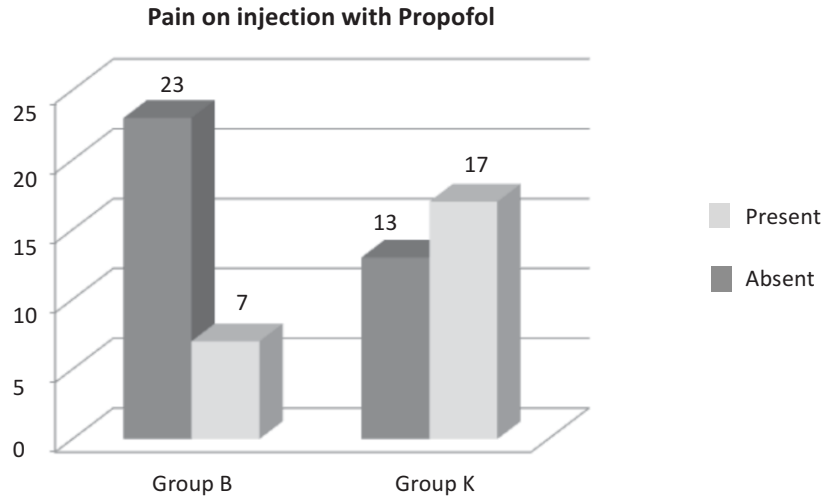

Fig 4: Intergroup comparison of pain on injection with Propofol

POS	Group B		Group K		Total		p value	Inference
	N	%	N	%	N	%		
Absent	21	70.0%	26	86.7%	47	78.3%	0.209	Not Significant
Present	9	30.0%	4	13.3%	13	21.7%		
Total	30	100%	30	100	60	100%		

Table V: : Intergroup Comparison of Post operative sedation

POS - Post Operative Sedation

PONV	Group B		Group K		Total		p value	Inference
	N	%	N	%	N	%		
Absent	22	73.3%	26	86.7%	48	80.0%	0.333	Not Significant
Present	8	26.7%	4	13.3%	12	20.0%		
Total	30	100%	30	100	60	100%		

Table VI: : Intergroup Comparison of Post operative sedation

PONV - Postoperative Nausea and Vomiting

DISCUSSION

Total intravenous anaesthesia has been a subject of interest for all anaesthesiologists. TIVA was initially attempted with a single drug (eg: thiopentone, propofol) but was associated with side effects and no drug was found to give complete anesthesia[10]. Therefore various drugs have been used individually or in combination with the other drugs to produce desired results[5]. There is a perceived wisdom that their plasma drug concentrations needed to produce anesthesia has to be reached quickly and maintained over the period of time that anesthesia. They should have rapid clearance rate and little delay between change in infusion rates, plasma levels and pharmacological actions. This allows rapid induction, good plane of surgical stage of anaesthesia and at the end of surgery, smooth emergence and early recovery[3]. Propofol is a commonly used induction agent in day care procedures. When used as a sole agent, require a larger dose of propofol and may be associated with haemodynamic and respiratory effects like hypotension, bradycardia, apnoea or hypoventilation. Ketamine, and opoids like butorphanol, may be combined to decrease the above mentioned adverse effects as they do increase blood pressure, heart rate, cardiac index and simultaneously decrease the amount of propofol needed[7,8].

In this study, in Ketamine group, there was statistically significant change in mean arterial pressure, heart rate and SPO_2 during post induction and maintenance of anaesthesia throughout the procedure when compared to Butorphanol group.

Similar study conducted by Nalini K B, and et al. compares propofol and Ketamine versus Propofol and Fentanyl in terms of haemodynamic stability and analgesia has concluded that the combination of ketamine and propofol is a safe and possibly superior alternative to propofol – fentanyl combination, in terms of haemodynamic stability[11]. Likewise Turk HS and et al. study on ketamine propofol combination vs opioid-propofol combination showed the same result[12].

Furuya A, et al. investigated for arterial pressure changes during the induction of anaesthesia with propofol by adding intravenous ketamine in 12 patients. Authors concluded that administration of ketamine before induction with propofol preserved haemodynamic stability in terms of blood pressure and heart rate compared with induction with propofol alone[13].

In the present study in comparision to Propofol-ketamine group, Propofol-Butorphanol group had statistically significant decrease in SPO_2 after induction and during maintenance phase of anaesthesia but no any significant difference in PONV. Similar study conducted by Aasim SA, Syamasundara RB, Zubair SI on 50 patients, propofol–ketamine group had better haemodynamic stability without respiratory depression and no postoperative nausea and vomiting than propofol fentanyl group[14].

Pain on injection with propofol is attenuated by various methods like injection of propofol in carrier fluid, large vein, and use of xylocard, analgesics and anaesthetic drugs. Of the 2 groups studied, butorphanol group enabled to abolish the pain on injection with propofol. Incidence of pain was 23.3% in Butorphanol group, where as in ketamine group it was 56.7%. This is consistent with study done by Agarwal and coworkers[15], where they found that simple and effective method of attenuating propofol induced pain is with pretreatment by butorphanol.

There was no statistical significant difference in PONV and sedation among the two groups.

CONCLUSION

This study concluded that Propofol-ketamine (Group K) combination has the advantage of offering better hemodynamic and respiratory stability. Attenuation of pain on injection is the only added advantage of propofol–butorphanol (Group B) combination whereas postoperative recovery in terms of sedation and PONV is similar among them.

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Evaluation of Prophylactic Antibiotic in Caesarean Section

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ABSTRACT:

Introduction: Caesarean section is one of the most rewarding surgeries when performed in time and indication. The number of C/S has been growing rapidly in the developing as well as developed world. **Aims & Objectives**: Evaluation of prophylactic antibiotic in caesarean section. **Methodology**: This study was conducted in Nepalgunj Medical College Teaching Hospital, Kohalpur from June 2014 to September 2014. Group A consisted of 100 patient who were randomly allocated & injection ceftriaxone 1gm. I/V stat was given at the time of induction of anaesthesia (30 mins. before incision). Group B also consisted of 100 patients who were given 5 days antibiotics. **Results**: In post operative evaluation the infection rate were compared in both groups, group A wound infection 2% and group B 3% , Endometritis - group A 1% and group B 2%, UTI- group A 3% and group B 4%, Fever - group A 6% and group B 4%. **Conclusion**: Single dose prophylactic antibiotic is comparable to multi dose antibiotic in this study. Since the single dose antibiotic is as efficacious as multi dose regime, it is advocated that single dose prophylactic antibiotic can be given in caesarean section as it is cost effective and as efficient as multi dose regimen.

Key words: *Caesarean section, endometritis, fever, prophylactic antibiotic, UTI*

INTRODUCTION:

Caesarean section is one of the most rewarding surgery when preformed in time and indication. The number of caesarean section has been growing rapidly in the developing as well as in developed world. The increase in routine caesarean section has been a global phenomenon. The concern has been expressed at the growing rate of caesarean section in some countries with some referring to it as emerging "global epidemic". In 1985 the WHO issued a consensus statement suggesting that there is no additional benefits associated with a caesarean section above 10-15%. Caesarean section deliveries may have serious implication for the health of the women undergoing them. The risk of post-partum death is 3.6 times higher after caesarean section than after vaginal delivery.

Before the mid-nineteenth century surgical procedures commonly resulted in post-operative sepsis and death. In the 1860s, when Joseph Lister introduced the principles of antisepsis, the incidence of post operative infection fell markedly from 50% to 15%. In the 1960s, using an animal model, Burke demonstrated that if antibiotics were given before wound contamination, the rate of infection decreased[1]. Following caesarean delivery the maternal mortality and morbidity may result from a number of infections including endometritis, urinary tract infection (UTI) and surgical site infection (SSI) which if deep rather than superficial, increases hospital stay and cost per case[2,3].

Prophylactic antibiotics have been shown to reduce the rate of surgical site infection. SSI accounts for 15% of nosocomial infections .The two more frequent complications of caesarean and hysterectomy surgeries are fever and SSI. Many studies have published in recent years stressing the need for antimicrobial prophylaxis both in hysterectomy and caesarean section. Although serious complications are uncommon, a literature survey demonstrated that prophylactic antibiotics significantly reduced the risk of endometritis and wound infection[4].

The prophylactic antibiotic in Nepalgunj medical college teaching hospital is not standardised and determined by the consultant incharge of the case. A prospective trial was performed to compare single dose pre-incisional antibiotic with regular antibiotic.

Material & Methods

This is a comparative prospective hospital based study conducted in Nepalgunj Medical College Teaching Hospital, Kohalpur in the department of Gynaecology and Obstetrics from June 2014 to September 2014. Women who were scheduled to undergo caesarean delivery were enrolled in this trial. The caesarean was considered elective when the procedure was performed in the absence of labor and before rupture of membrane. Patients received information about objective concerning objectives of our trial prior to surgery and written consent was obtained. The study protocol was approved by the ethical committee of the hospital.

Patients were divided in 2 groups (Group A and Group B) each consisted of 100 patients. In group A, the patients were

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randomly allocated and injection Ceftriaxone 1gm. Intravenous stat. was given at the time of induction of anesthesia (30 mins. before incision). In group B, patients were given 1 day intravenous antibiotics (ampicillin and metronidazole) followed by oral for next 4 days. After surgery patients were assessed daily. Two main outcome of this study were fever and infection. Febrile morbidity was defined as temperature of ≥ 100.4°F recorded at least on two successive occasions 6 hours apart, excluding the 1st 24 hours of surgery. Infection of one or more sites were diagnosed by clinical symptoms, signs and laboratory tests. The infection included pelvic cellulitis, UTI, abdominal wound infection. Caesarean section group was followed up for the development of endometritis (i.e. fever, uterine tenderness and offensive lochia). All variables were analysed and data were entered in SPSS version 22 for descriptive and analytical study. A p value of <0.05 was considered significant.

RESULTS

Age (years)	Group A	Group B
No. patients mean age in Years (SD)	30.95±8.42	28.7±5.44
BMI in kg/m² (SD)	21.9±2.22	23.3±2.34

Table I: Charateristic of patients in two surgical groups

	Group A	Group B
Mean duration of operation mins.	41 mins.	45 mins.
Mean blood loss ml.	600	650
Mean days of catheterisatic	1	1

Table II: Risk factor for developing post-operative infection

	Group A	Group B	p value
Wound infection	3	2	0.50
Endometritis	1	2	0.50
UTI	3	4	0.341
Fever	6	4	0.26

Table III: Incidence of post-operative infection

DISCUSSION

Many studies have supported antimicrobial prophylaxis guidelines. More over there is great variation in use of antibiotic prophylaxis, so in our study we used injection ceftriaxone 1 gm. for single dose in group A and injection ampicillin and injection metronidazole for 1 day followed by oral antibiotics in group B. Following antibiotic prophylaxis, wound infection was found to be 3% in group A and in contrast 2% in group B with overall P value 0.50. Most of the authorities suggest prophylactic antibiotic should be considered for all elective caesarean deliveries in which the combined incidence

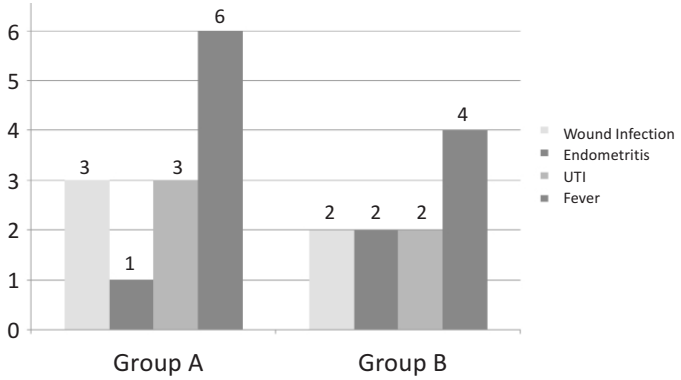

Figure 1: Bar chart showing the outcome of complications in both the groups

of endometritis and wound infection exceeds 5%[5]. In this study, endometritis was 1% and 2% in group A and B respectively with overall P value 0.50. Similarly incidence of UTI was 3% in group A and 2% in group B with P value to be 0.34. Fever was 6% in group A and 4% in group B and P value was 0.26. The incidence of post- caesarean infection was similar when compared with other studies[6,7]. The prospective study confirms that single dose antibiotic prophylaxis had a beneficial effect on women undergoing elective caesarean section where as similar rate of complications were observed in multiple dose antibiotic for 5 days.

CONCLUSION

Single dose prophylactic antibiotic is comparable to multi dose antibiotic in this study. Since the single dose antibiotic is as efficacious as multi dose regimen, it is advocated that single dose prophylactic antibiotic can be given in caesarean section as it is cost effective and as efficient as multi dose regimen.

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Rheumatic Fever & Rheumatic Heart Disease: Azithromycin Must Replace Penicillin for Treatment and Prophylaxis

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ABSTRACT

The standard and age-old treatment of RF/ RHD is a single injection of Benzathine Penicillin G given intramuscular after sensitivity test in a dose of 1.2 million units. For secondary prophylaxis, this is followed by Injection Benzathine Penicillin given intramuscular, each time after sensitivity test, after every 21 days (3weeks), in the same dose of 1.2 million units. The treatment and prophylaxis of RF/ RHD has never seriously been reviewed in the light of newer drugs discovered for GAS (Group A Streptococcus) after Penicillin. All the other drugs mentioned above are oral forms which could never be an alternative to Benzathine Penicillin due to the daily dose required, except for Azithromycin which has a long half-life and several other pharmacological properties which make it an ideal drug for treatment and prophylaxis of RF/ RHD. Benzathine Penicillin G is in use for past 60 years due to convenience of dosing, its undoubted efficacy in eradication of the GABHS, and the low cost. But the scene is changed now.

We must replace the use of Penicillin with a suitable drug, and never look back, for reasons detailed below.

Acute Rheumatic Fever (ARF) usually affects children aged 5 to 15 years, but recurrences of attacks with rheumatic activity or ongoing inflammation and intervals of rapid progression of valvular disease continue up to age 40 and even beyond. Rarely may it be detected for the first time even at the age of 50 years and beyond. ARF begins with a respiratory tract infection usually a sore throat caused by Group A Beta Haemolytic Streptococci (GABHS).

As there is no specific or definitive test for ARF, diagnosis is made by a combination of clinical features and to great extent the physician's discretion. For Rheumatic Heart Disease (RHD), the single most confirmatory evidence is the Echo Doppler Study. The standard and age-old treatment of RF/RHD is a single injection of Benzathine Penicillin G given intramuscular after sensitivity test in a dose of 1.2 million units. For secondary prophylaxis, this is followed by Injection Benzathine Penicillin given lntramuscular, each time after sensitivity test, after every 21 days (3weeks), in the same dose of 1.2 million units.

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Prevention of Rheumatic Fever (RF)

There is no treatment of ARF that has been proven to alter the likelihood of developing, or lessened the severity of RHD. In a study of 1790 patients from 11 countries, RF recurred in 8 (.45%) in those who received Benzathine Penicillin prophylaxis compared with 11 of 96 (11.5%) who did not comply[1]. This shows that recurrence may occur even with best prophylaxis and that compliance is very important. So at best, our attempt should be to eradicate the GABHS infection at the outset and give maximum symptomatic relief possible to the patient.

The non-drug prevention of RF / RHD, like improving socio economic Conditions, housing, sanitation, overcrowding has not been possible in developing nations where RF /RHD is a major health problem. So the mainstay of primary prevention is timely and appropriate drug treatment.

The drug of choice for the past 60 odd years has been Penicillin in different forms namely: Phenoxymethyl Penicillin 500mg oral twice daily or Amoxycillin 1g daily divided in 3 doses, Injection Procaine Penicillin IM twice a day, or Benzathine Penicillin G single dose IM 1.2 million units. Alternative to above drugs are Erythromycin, Cephalosporins like Cefadroxil, Cephalexin, Cefuroxime axetil, Cefpodoxime proxetil, Cefdinir, and Tetracyclines, Sulphisoxazole, Sulphadiazine, macrolides and Azalides etc. All above drugs have a big list of disadvantages of using in RF / RHD.

If this treatment is started within 9 days of onset of sore throat almost all cases of ARF will be prevented. This fact is extremely important if we want to shift to a better drug for primary prevention and also to treat recurrent attacks of ARF as well as for the secondary prevention in terms of safety, availability, compliance, efficacy, affordability and tolerability. The only drug with all these properties is Azithromycin. Ordinarily, sore throat whether viral or Streptococcal (GAS - Group A

Streptococcus), resolves in 3 to 5 days but if we have to prevent RF/ RHD, then all cases of sore throat even if cured or relieved of symptoms must be given the full course of Azithromycin 500mg (12mg/Kg) once daily for 5 days[2].

Secondary Prevention of RF

Long term secondary prophylaxis is advocated in RF/RHD, as a known patient of RF is at higher risk for recurrent attacks of RF and progression of valvular heart disease than the general population. The best known antibiotic up till now has been Benzathine Penicillin G 1.2 million units given at interval of 3 to 4 weeks (with more data to support 3-weekly intervals). The treatment and prophylaxis of RF/ RHD has never seriously been reviewed in the light of newer drugs discovered for GAS (Group A Streptococcus) after Penicillin. All the other drugs mentioned above are oral forms which could never be an alternative to Benzathine Penicillin due to the daily dose required except for Azithromycin which has a long half-life and several other pharmacological properties which make it an ideal drug for treatment and prophylaxis of RF/ RHD. Benzathine Penicillin G is in use for past 60 years due to convenience of dosing, its undoubted efficacy in eradication of the GABHS, and the low cost. But the scene is changed now.

We must replace the use of Penicillin with a suitable drug, and never look back, for the following reasons:

- Patients of RF/RHD are usually from the villages who first go to their family doctor or CHC for treatment. For the past two decades, with the gradually increasing distrust of the patients for the doctors and with the Consumer Protection Law for medical practice, the doctors, paramedics and the nurses have become very fearful of giving injections of Penicillin due to the severe fatal reactions which occur in more than 1 in 10,000 patients, which is not a small number by any means Considering that there may be more than 20 million people affected by RF/ RHD in the world today (AHA Scientific Statement Circulation March 24, 2009)[3].
- Also, this drug Benzathine penicillin has become very difficult to procure and the patients have many a times to buy it in the black paying many times the cost of the drug.
- They have to travel long distances in search of some person who will be ready to give them the injection, knowing the hazards. Even big hospitals, district hospitals and medical college hospitals refuse to give these injections due to the sudden severe reaction causing death of the patient or, they do so only after getting signed consents of the relative saying that they, are well aware and are prepared for the fact that their child (relation) may well drop down dead after the prick (even after-proper sensitivity test each time that the injection is administered).
- We have come a long way from those days when there was no option apart from penicillin oral or injectable and it was a 'take or die' situation. Today when the patient's parents ask Doctor, is there any other option? - then one can't say - no, that's the only drug if you want to save your child.
- After an injection of Benzathine Penicillin, invariably the patient, usually a small child suffers from aches and pains all over and especially at the site of injection; fever, which does not recover any sooner than it's time for next injection.
- The injection itself is oily and painful and more than 2 ml in quantity. It has to be given deep intramuscular whereas the patients of RHO are usually from poor socioeconomic strata, very cachectic and malnourished with poor muscle mass.
- There are frequent cases of patients showing transient valvulitis of mitral and aortic valve after injection of Benzathine Penicillin.[4] So ironically this becomes a cause for continuing' the injection for say another 5 years and then the patient ends up with the injection being prescribed lifelong. [May be this is the reason that there are recommendations for giving it lifelong].
- Some drugs which interact with penicillin include warfarin, aspirin, tetracycline, diuretics etc. These are commonly coprescribed drugs in patients of RF / RHD.
- Benzathine penicillin is not for IV use at all. Inadvertent IV injection can cause cardiorespiratory arrest and death.
- Hypersensitivity and allergic reactions, immediate and delayed are common.
- It should not be injected near a nerve, artery or vein.
- Pseudomembranous colitis is common with penicillin.
- Clostridium difficile associated diarrhoea (COAD) occurs which can increase the morbidity and mortality.
- There is enough evidence and experience with Benzathine Penicillin to show that it itself causes all features of ARF like fever, arthritis and even valvulitis, not to mention the well known fatal anaphylaxis risk[4].

There is ample scientific supporting literature for all of the above.

All the above problems result in total noncompliance leading to the progression of valve destruction and death of the patient. Any amount of counseling also does not help as the patients and attendants are more terrified of the injection and its consequences compared to the pains and agony of the disease itself, which they realize will progress relentlessly sometimes irrespective of years of painful prophylaxis.

The solution is to give tablet Azithromycin 500 mg once daily for 5 days consecutively as initial treatment, and then 1 tablet of Azithromycin 500 mg only once a week i.e. say every Sunday morning for 1 year only.

In our institution this antibiotic with more or less similar regime has been in use for 8 years and found to be nearly 100% effective in terms of almost no relapse, recurrence or new cases of RF and RHD, nearly 100% compliance and freedom from side

effects. It may be given for more than 1 year if at all there is sore throat or relapse of the disease i.e. any of the symptoms of disease or any suspicion thereof, for an extended period according to the discretion of the treating doctor.

This regime has been worked out with the following facts for backup and rationalization:

- The basis of giving Azithromycin only once a week is the long half-life of the drug which is sufficient to eradicate GAS, and suppress any autoimmune inflammatory process in the heart which may start mid-week, when the drug is given at weekend.
- Azithromycin is acid-stable and so can be taken orally without damage from gastric acids. It is readily absorbed, but its absorption is greater on an empty stomach. Azithromycin can be taken with or without food.
- Time to peak concentration is 2.1 to 3.2 hours for oral dosage, and 1-2 hours for IV forms.
- Due to high concentration in phagocytes Azithromycin is actively transported to site of infection. During active phagocytosis large concentration of Azithromycin is released.
- The concentration of Azithromycin can be 50 times higher in the tissues than in plasma. This is due to ion-trapping and high lipid solubility of the drug. Concentrations in target tissues such as lungs and tonsils exceed the MIC 90 after a single dose of 500 mg. The single daily dose administration is a big advantage.
- Azithromycin is the first of a class of antibiotics designated chemically as azalides. The chemical name of Azithromycin is 9-deoxy9-za9-a-methyl-9-ahomoerythromycin.
- The molecular weight is 749.0.
- The mode of action of Azithromycin is inhibition of protein synthesis in bacteria by binding to 50s ribosomal subunit and preventing translocation of peptides
- Azithromycin's long half-life allows a large single dose to be administered and yet maintain bacteriostatic levels in the infected tissue for several days.
- Following a single 500mg dose, plasma concentration of Azithromycin declines in a polyphasic pattern with a mean apparent plasma clearance of 630 mL/min and a terminal elimination half-life of 68 hours. The prolonged terminal half-life is thought to be due to extensive uptake and subsequent release of drug from tissues.
- The drug persists in the tissues for 6 days if started with continuous 5-days treatment.
- Hence Azithromycin needs to be given only once a week as it has a long life of 6 days if given after loading dose for 5 days. Thereafter it can be given in a dose of 1 tablet weekly only. All other antibiotics need to be given daily, therefore Azithromycin is the best choice.
- But each time, the drug must be started with 1 tablet of 500mg continuously for 5 days even when switching over from other antibiotics.
- Azithromycin also has immune-suppressant properties.
- Azithromycin is freely available, safe in children and adults alike, cost effective, and has excellent anti-streptococcal activity.
- It is effective in complete eradication of streptococci from oropharynx and subsequent prevention of RF RHD. Caution-should be exercised when administered to patients with renal failure.
- It can be safely given even in moderate hepatic impairment. In children it can be given as a single dose of 10 mg/kg or 20mg/kg for 3 days only, with good efficacy. A daily dose of 500 mg may be given to any child more than 5 years of age.
- During pregnancy no evidence of harm to the fetus due to Azithromycin was found.
- Azithromycin was discovered in 1991 and is in constant use for GAS since then with excellent results. In a systematic review of 21 randomized controlled trials Azithromycin 20 mg/kg/day (3-day) achieved bacteriological eradication in 95% cases in acute streptococcal tonsillopharyngitis[5].

In a study downloaded from http:\circ.ahajournals.org/ dec16, 2011,730 patients were given Azithromycin for ARF in dose of 500 mg once a day for 5 days then 500 mg on 2 consecutive days of the week i.e. only 2 days in a week. No patients showed relapse or rebound rheumatic activity or re infection with streptococci, there was no worsening of cardiac valve disease either. Compliance was 100%. Patients who had no new problem attributable to RF/RHD were given Azithromycin prophylaxis for one year only. Thus it was shown that Azithromycin is very effective in treatment and prevention of RF/ RHD due to efficacy of treatment and high compliance[6].

In a communication to Prof. A. Lalchandani, Dr. Stephen Marko of World Heart Federation, University of Connecticut has mentioned that there is great concern over the use of Benzathine Penicillin G due to significant issues with quality and quantity of the drug with reports of shortages and poor quality penicillin. He echoes the sentiments that the treatment guidelines should be less stringent and according to the needs of the community. (Stephen.Marko@worldheart.org - Dec. 6, 2011-survey based study on BPG).

According to an article in Paediatric Cardiology, 2010 August, from the Division of Cardiology, Department of Paediatrics of University of Virginia, a retrospective review of patients of ARF <21 years was performed. 144 patients of RF/RHD showed n recurrence rate of 38%, mean level of compliance with Benzathine penicillin was 59% in patients without recurrence of ARF, and 57% in patients with recurrence of ARF. This suggests that improved methods of primary and secondary antibiotic prophylaxis for ARF must be researched[7].

The recurrence rate for RF in various studies is 3% to 8% over 5-6 years but rate of recurrence of RF in studies with

Azithromycin was less than 3% consistently. A serum penicillin concentration of more than 0.02 µgm/ml is required to prevent recurrence[8] but since Azithromycin persists in tissues in high concentrations therefore its efficacy is greater in preventing recurrences.

There is no rationale for giving RF /RHD prophylaxis for more than 1 year after an episode of sore throat, recurrence, relapse of evidence of progression of disease. If Azitrhomycin is started within 9 days of sore throat, it will prevent all cases of RF/RHD. Various studies have proved that it takes at least two weeks after a streptococcal infection / sore throat for autoimmune destruction leading to RF /RHD. Even in post streptococcal reactive arthritis valvular heart disease is seen only several months after the streptococcal infection in a small proportion of patients. These patients should receive secondary prophylaxis for up to 1 year after symptoms (Class llb, LOE CAHA Scientific Statement)[3].

The duration of prophylaxis according to American Heart Association Recommendations is from 5 years after last attack to lifelong prophylaxis in patients with persistent valvular disease, with a footer that the recommendations be modified by individual circumstances as warranted[8]. It is very obvious from the footer that the duration of treatment recommended has been arbitrarily decided and not after serious deliberations over the strep infection, a possible time-interval for causing an autoimmune damage, its time gap for presenting as carditis or organic heart valve destruction, its persistence and disappearance from the blood stream, its susceptibility to the drug and comparison with other drugs.

Can any benefit be attributed to a drug which has to be taken lifelong and can it truly be called 'prophylaxis'. An ethical prescription should be based on the principle of 'greater benefit of the drug than the risk from its use' and what greater risk than death ..... as can occur with injection Benzathine Penicillin; and what greater benefit than 95% eradication of causative organism!

What are we waiting for? There cannot be a better, more effective drug for GAS than Azithromycin (CIassl, LOE-C). Should we not all shift to Azithromycin for prophylaxis ? Can there be better proof than 8 years of consistent and exclusive use of this drug for treatment and prophylaxis of RF and RHD in our GSVM Medical College and associated hospitals catering to a huge urban and rural population in and around Kanpur districts where most of the patients are from lower socioeconomic strata and the incidence of RF/RHD is not less than 4 per thousand, still significantly high[6,10]. As we strongly considered the use of Benzathine· Penicillin injections unethical, dangerous, less effective and even harmful, with probability of fatal reactions, a direct comparison of Behzathine Penicillin and Azithromycin could not be done but in vitro comparison result show Azithromycin to be a superior drug for GABHS, the causative organism of RF/ RHD[11].

The best safest and most effective treatment and prophylaxis of RF and RHD today is **Tab Azithromycin 500 mg one daily for 5 days continuously followed by one tablet of Azithromycin 500 mg once a week for one year only**.

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