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Dr.Mrs.S.G.Bhatia

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How many doctors do we really need?

Before three years, Medical Council of India's President and entire executive committee was dissolved by central government for the reason of rampant corruption. Later board of governors was appointed to look after the work of MCI. The first board of governors under the chairmanship of Dr.Sarin proposed to establish 500 new medical colleges in India to produce adequate number of doctors to cater to the need of India's people. As a result various norms related to opening of new medical college were also relaxed[1]. These include: a) Land requirement reduced from 25 acres to 10 acres b) 900 bedded hospital instead of 1500 bedded hospital fro a college with admission capacity of 250 c) Hostels can be in the radius of 5km from the college and d) age of teacher to be recognized as a teacher increased from 65 to 70 years. MCI also has now made DNB degree at par with MD/MS; against which it was fighting fiercely for many decades! It is postulated that in India there is deficiency of around 800000 allopathy doctors. MCI also wants to increase the admission capacity of existing medical colleges from 150 to 250. This year seats have been increased to the extent of 1400 throughout India.

The first issue is how one can decide the number of doctors required by a country. Second issue is who should be responsible for deciding this and third issue is whether they are performing this responsibility correctly or not.

In an answer given by the then state minister for health, Mrs.Panabakka Laxmi India had 1 allopathic doctor for 1722 people in 2005. If doctors from other pathies are counted then the doctor population ratio becomes 1: 781! It was informed that India had 6,38,792 allopathic doctors and every year some 34000 doctors pass out from medical colleges annually[2]. Considering this data as the base one can say that in 2010 we had 800000 allopathic doctors and the doctor- population ratio was 1: 1400.

The need for doctors can be decided by the disease load in the country, the hours of work of an average doctor etc. World Health Organization in its course book “Guide for Health Manpower Planning” has described four methods for deciding number of doctors required by a country[3]. One method is “Health needs” method which takes into account the optimum services required by the country for achieving standard health care. In “Service target” method, the number of doctors is decided by the types of health services, its quantity and quality. In “Health or economic demand” method, the projection regarding required number of doctors is made by social structure, income and attitudes related to health in the society. In fourth method arbitrarily the number of doctors required is decided on the basis of population of the country. This is the simplest but crude method to decide about required number of doctors.

One must understand that India should not want 1 doctor for 1000 population as Cuba has 1 for 250 people! More doctors in a society do not mean that the society is healthier. High Level Expert Group (HLEG) for Universal Health Coverage constituted by Planning Commission of India recommended that doctor population ratio should be 1:1000[4]. The basis for this is coverage of measles immunization and births conducted by skilled attendants. The issue is more complex. Many states in India have achieved health indices of global standards with much lower doctor population ratio[5].

The peculiarity of India

India is the only country in the world where there are doctors from other pathies of medicine who provide health care to the community. Cross practice is rampant and the general practice sector is mostly captured by these doctors from other pathies. It is rare to get a plain MBBS doctor having general practice. The number of such doctors is huge; almost equal to the number of allopathic doctors.

India has a paucity of doctors belonging to different specialty and super specialty. We have shortage of psychiatrists, cardiologists, nephrologists, skin specialists, radiotherapists etc.

India is a vast country and different states have different doctor population ratio. States like Maharashtra and Karnataka have much better doctor population ratio than the states of north east and UP, Bihar etc.

There also is a great disparity between urban and rural areas.

So in deciding number of doctors required by our country, rather than WHO standards and norms we should concentrate on our manpower in the form of AYUSH doctors who are mostly into general practice. It appears that we have adequate doctors if we calculate doctor population ratio taking into account these doctors.

Secondly the norms regarding opening new colleges should be related to situation in that state. There cannot be an "All cure" solution for all states.

Definitely we need more specialists. Attempt should be made to increase post graduation seats in all medical colleges.

The trend to increase more medical colleges will result in excess number of doctors than the society can sustain. This will ultimately result in increased malpractice in place of better health!

The statement of the editor of Singapore Medical Journal is worth reading in this context!

He wrote in regarding "Doctor Requirement" in December 1962 issue[6]- "All these go to show the danger of calculating medical needs on an arbitrary figure. The matured way of meeting a problem of this nature is to utilize available facilities efficiently and without waste, and not to plan a mansion with the possibilities of a flat to bemoan the inadequacy of resources. The former means healthy and economical planning and the latter a perpetual debt like hire-purchase in an improvident family which must in the end come to grief with the Frankenstein it created. Medical need is a pressing item that all reasonable men must be interested in, but unless we cut our dress according to the cloth, such intent may not at all be a happy augury".

It is necessary for the MCI to read this statement before actually spoiling the health care scenario in this country!

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J V Dixit
Government Medical College Aurangabad

ORIGINAL ARTICLE

"Evaluation Of Spinal Cord & Vascular Injuries With MRI In Acute Spinal Trauma"

Gajbhiye. M.I, Shetty. A.M, Khadse. G.J.

Department of Radiodiagnosis, B.J.M.C Pune.

ABSTRACT

TITLE: Evaluation of spinal cord & vascular injuries with MRI in acute spinal trauma

Dr Meenakshi Gajbhiye Professor, Dr Amit Shetty Assistant Professor, Dr G.J.Khadse Professor.

AIMS AND OBJECTIVES: Evaluation of spinal cord and vascular injuries and clinical correlation

MATERIALS & METHODS: 1.5 tesla GE MRI machine is used for study.

Coil : Standard spine coil. Recommended sequences are:- T1 & T2- axial, T1 &,T2-sagital, Axial-GRE, Coronal-STIR. 200 patients with history of spinal trauma with indications for MRI are assessed.

DISCUSSION: Cord compromise, cord edema, EDH and vascular injuries are more common with RTA and fall from height. Cord oedema associated with hemorrhage shows a significant association with severe clinical symptoms as compared to isolated cord oedema. All six patients with vascular injury were asymptomatic & detected incidentally.

CONCLUSION: Spinal cord oedema with hemorrhage in combination showed a significant association with clinically severe symptoms as compared to only spinal cord oedema. Cord hemorrhage is associated with poor prognosis. Moderate symptoms are more common with isolated cord oedema. It is imperative to look for vertebral artery flow voids in every spinal trauma patient. Most common type of spinal cord injury is cord oedema. RTA and fall from height are commonly associated with severe spinal cord injury.

Aims And Objectives

Evaluation of spinal cord and vascular injuries with MRI and its clinical correlation.

Introduction

This study is carried out in Dept of Radiodiagnosis, at B.J.Medical College and Sassoon General Hospital, Pune. MRI is unparalleled investigation for imaging of spine in patients of spinal trauma. MRI is routinely used in evaluation in patients who have focal neurological deficit. The major causes of spinal injury include motor vehicle accidents, fall from heights, animal injuries, water sports injuries, medico-legal injuries and slip injuries. The goals of imaging include detection of cord injury, cord compression, vascular injuries, to aid in surgical planning and determining potential for instability. A spinal cord compression should be operated within 24 to 48 hours so that maximum recovery of neurological function is possible. Hence MRI forms an important investigation in management protocol of trauma patients.

Materials & Methods

1.5 tesla GE MRI machine is used for study.

Coil : Standard spine coil. Recommended sequences are:- T1 & T2- axial, T1 & T2-sagital, Axial-GRE, Coronal-STIR. Total 200 symptomatic patients with history of acute spinal trauma are assessed with MRI and the findings are correlated with clinical symptoms.

Observation & Results

Cord injuries are evaluated as oedema, hemorrhage, compression, EDH & findings are correlated with age, gender, type of injury & clinical symptoms according to its severity.

Table no 1: Cord injuries in relation to age, gender

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Dr Gajbhiyee, Department of Radiodiagnosis, B.J.M.C Pune.

Cord Injury	No of Patient	Gender		Age group			
		F	M	01-20	21-40	41-60	61 - 80
Compromised	40 (20)	5 (12.5%)	35 (87.5%)	5 (12.5%)	16 (40%)	13 (32.5%)	6 (15%)
Oedema	67 (33.5)	6 (9%)	61 (91%)	5 (7.4%)	31 (46.3%)	23 (34.3%)	8 (12%)
Hemorrhage	19 (9.5)	2 (10.5%)	17 (89.5%)	1 (5.2%)	12 (63.2%)	6 (31.6%)	0
EDH	13 (6.5)	1 (7.7%)	12 (92.3%)	1 (7.7%)	8 (61.5%)	4 (30.8%)	0

In our study, in total 40 patients with cord compromise 87.5% are males and 12.5% are females. Most commonly affected age group is 21-40 years (40%) followed by 41-60 years age group (32.5%) and minimally affected age group is 1- 20 years (12.5%).

In total 67 patients with cord oedema, 91 % are males and 9 % were females. Most commonly affected age group is 21-40 years (46.3%)

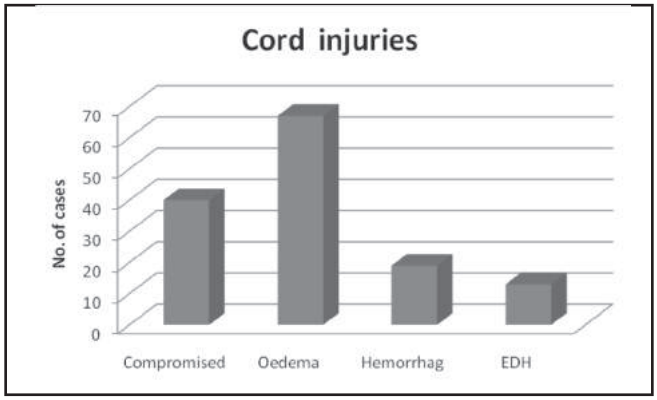
followed by 41-60 years age group (34.3%) and minimally affected age group is 1- 20 years (7.4%).

In total19 patients with cord hemorrhage, 89.5 % are males and 10.5 % are females. Most commonly affected age group is 21-40 years (63.2%) followed by 41-60 years age group (31.6%). No patient is seen in 61-80 age groups.

In total 13 patients with epidural hemorrhage, 92.3 % are males and 7.7 % are females. Most commonly affected age group is 21-40 years (61.5%) followed by 41-60 years age group (30.8%). No patient is reported in 61-80 age groups.

Table no 2: Cord injuries in relation to Type of injury.

Cord injury	No of Patients	Type of injury			
		Fall from height	RTA	Slip injuries	Others
Compromised	40 (20%)	14 (35%)	15 (37.5%)	9 (22.5%)	2 (5%)
Oedema	67 (33.5%)	27 (40.3%)	22 (32.8%)	14 (20.9%)	4 (6%)
Hemorrhage	19 (9.5%)	5 (26.3%)	9 (47.4%)	3 (15.8%)	2 (10.5%)
EDH	13 (6.5%)	8 (61.5%)	3 (23%)	1 (7.75%)	1 (7.75%)



In total 40 cord compromise patients maximum number are from RTA constituting 37.5% followed by fall from height 35% and slip injury constituting 22.5% whereas "other" type of injuries are minimum constituting 5%.

Out of 67 cord oedema patient's maximum number of patients are from fall from height constituting 40.3% followed by RTA 32.8% and slip injury constituting 20.9 % whereas patients from "other" type of injuries are minimum constituting 6%.

Out of 19 cord hemorrhage patient's maximum number of patients are from RTA constituting 47.4% followed by fall from height 26.3% and slip injury constituting 15.8% whereas patients from "other" type of injuries are minimum constituting 10.5%.

Out of 13 epidural hemorrhage patients maximum numbers of patients are from fall from height constituting 61.5 % followed by RTA constituting 23 % and 7.75% are from slip injury and "other" type of injury.

Cord compromise are more commonly with RTA and fall from height rather than slip injuries as compared to normal population. This association is highly significant. {Chi-square=14.42, df=2, P=0.0007}[1,2,3].

Cord oedema is also more common with RTA and fall from height rather than slip injuries as compared to normal patients. This association is highly significant {Chi-square=37.6, df=2, P<0.001}[1,2,3.]

EDH is also more common with RTA and fall from height rather than slip injuries as compared to normal patients. This association is highly significant. {Chi-square=17.2, df=2, P<0.001}[1].

Table no 3.

Co-relation of clinical features with cord oedema and hemorrhage.

Clinical symptoms	Oedema with hemorrhage	Only cord oedema
Normal/mild symptoms without neurological deficit	0	6
Moderate symptoms	4	32
Severe symptoms	15	10
Total	19	48

Maximum numbers of patients of isolated cord oedema are associated with moderate symptoms whereas severe symptoms are seen in oedema & hemorrhage together.

Normal/mild symptoms without any neurological deficit are seen with isolated cord oedema which is uncommon with cord oedema & hemorrhage together.

Cord oedema & hemorrhage together shows a significant association with severe clinical symptoms as compared to isolated cord oedema. This association is highly significant. {Chi-square =19.96, df=2, P<0.001}[4,5.6,7,8,9,10,11,12]

Table no 4: Clinical features in relation to Type of injury

Clinical features	No of Cases	Type of injury			
		Fall from height	RTA	Slip injuries	Others
Normal/Mild symptoms without neurolcgical deficit	118 (59%)	7 (5.9%)	31 (26.3%)	75 (63.6%)	5 (4.2%)
Moderate clinical features (Reduced Power, tone)	55 (27.5%)	25 (45.5%)	13 (23.6%)	15 (27.3%)	2 (3.6%)
Severe clinical features (Absent power, tone, reflexes, sensory system)	27 (13.5%)	8 (29.6%)	10 (37.1%)	6 (22.2)	3 (11.1%)

Out of total 118 patients with normal/ mild symptoms without any neurological deficit, 63.6% have slip injury, 26.3% have RTA, 5.9% have fall from height and 4.2% have "other" type of injury.

In total 55 patients with moderate symptoms of neurological deficit, 45.5% have fall from height, 27.3% have slip injury, 23.6% have RTA and 3.6% have other type of injury.

In total 27 patients with severe symptoms of neurological deficit, 37.1% have RTA, 29.6% have fall from height, 22.2% had slip injury and 11.1% have "other" type of injury.

Severe symptoms of neurological deficit are significantly associated with fall from height followed by RTA and slip injuries. This association is highly significant. {Chi-square=43.2, df=2, P<0.001}[13].

Table No 5:

	Asymptomatic	Clinical features of vascular injury
Vascular Injuries	6	0

All vascular injuries diagnosed were unilateral vertebral artery thrombosis. None of the patients have any clinical features of vascular injury.

Discussion

All types of spinal cord injury are commonly seen in males than in females and in the common age group of 21-60 years[14,4,12.].

Spinal cord oedema is the most common type of spinal cord injury. This is consistent with studies by Khandelwal et al, Kulkarni et al & Mc Ardle et al.

Road traffic accidents and fall from height are associated with severe cord injuries [1,2]. Slip injuries are associated with less severe cord injuries. This association is statistically highly significant. Vinas et al and Smith et al also show road traffic accidents and fall from height to be associated with severe cord injury.

Severe symptoms are seen with cord oedema and hemorrhage together whereas isolated cord oedema have moderate clinical symptoms [4,15,16,14].

Cord oedema with hemorrhage shows a significant association with severe clinical symptoms as compared to isolated cord oedema. This association is statistically highly significant [4,17,6,5,14,18,19]. Spinal cord intramedullary hemorrhage at the time of injury is associated with poor prognosis[15].

Severe neurodeficit is associated with fall from height followed by road traffic accidents and less common with slip and "other" type of injuries[13,20].This association is statistically highly significant. Findings of Nalina et al, Roop Singh et al are consistent with our findings.

All six patients with unilateral vertebral artery injury did

not show any symptoms of vascular trauma & are incidental findings. Hence it is essential to look for the flow voids of vertebral artery in all cases of cervical spine injuries even if the patient does not show any neurological symptoms[23, 22,15,19]. Early signs of vertebral artery injury may be clinically silent [23,15,22,19] . Early recognition of vertebral artery injury remains important because of its potential to produce permanent neurologic damage[21,15,19].

Summary And Conclusion

- Most commonly occurring spinal cord injury is isolated cord oedema, followed by cord compromise, oedema & hemorrhage together & EDH.
- Road traffic accidents and fall from height are highly associated with severe spinal cord injuries while slip injuries are associated with mild & moderate spinal cord injuries.
- Spinal cord oedema with hemorrhage together have a significant association with clinically severe symptoms. Cord hemorrhage is associated with poor prognosis.
- It imperative to look for vertebral artery flow voids in every cervical trauma patient.

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Book Review

It is welcome news for medical students. The long awaited 4th Edition of "Text Book of Community Medicine" is now available. The authors seem to have taken special efforts in revising almost all chapters. Chapter on Biostatistics needs special mention. With the wide spread use of computers manual calculations are not necessary. Hence authors have resorted to teaching complicated calculations with the help of MS-Excel. Chapters on National Health Programs, Communicable Diseases, Epidemiology, Nutrition etc. all have a new look. The book is recommended as the text book of choice by The Maharashtra University of Health Sciences and by The D.Y. Patil University.

Entry of Dr. P.P. Doke and Dr. P.Y. Mulay in authors list is also a welcome change. Experience of Dr. Doke as Director of Health Services in Maharashtra has added new flavor to chapters like National Health Programs. Dr. Mulay is a well known teacher and physician. His contribution has given new dimension to chapters on Non-communicable diseases.

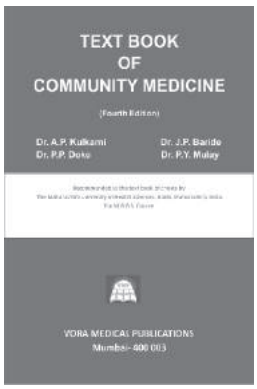
We strongly recommend this book for our medical undergraduates and post-graduates.

Dr. S.P. Rao

Professor, Preveentive & Social Medicine

BJ Medical Colllege

PUNE



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ORIGINAL ARTICLE

Rapid Psychological Assessment Of Depression And Its Relationship With Physical Health Among Urban Elderly

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ABSTRACT

Background: Old age is associated with increased occurrence of a wide array of Psychological impairments or losses, which might contribute to physical disabilities. Depression has been identified as the most common aberration. Rapid assessment of depression would be able to identify the quality of individual and family life of the elderly. **Objectives:** To assess psychological health status with respect to depression among geriatric urban community. The relationship of depression with health perception and physical health status has been explored. **Methods:** A cross-sectional total geriatric population survey consisting of 254 elderly has been carried out at urban field practice area. A standard geriatric depression scale (Short form) has been utilized to assess psychological status. Detailed physical examination and investigations with special reference to Diabetes, Hypertension and Visual defects was carried out. Data was analyzed to find out the relationship of various socio-demographic factors, physical morbidities with depression. **Results:** Out of 254 elderly examined, 32% females and 23% males were found to be suffering from depressive disorders. When assessed for individual health status perception, 25% felt to have good health. Out of 190 geriatric subjects perceiving fair to bad health, 110 were found to be suffering from depression ($p<0.001$). Depression was also found to be associated with history of hospital admission in the previous year ($p<0.05$), low vision ($p<0.05$), diabetes ($p<0.01$) and hypertension ($p<0.01$). **Conclusion:** Depression among geriatric age group is associated with physical illness and perception of health.

Introduction

Aging is a universal phenomenon. India is the second largest country in the world, with 72 million elderly persons above 60 years of age as of 2001[1,2]. Increase in life expectancy is attributed to enhance the proportion of elderly to around 20% by 2025 from the present 8%. The rapid changes in social structure, deteriorating joint families and in shattering Indian traditional value system will have tremendous psychological impact on the well being of these senior citizens as well as equilibrium of the society itself[3,4,5,6]. Against this backdrop it is reasonable to expect that the mental health problems specifically depression among elderly will grow in the years to come.

However, suitable early assessment and initiation of appropriate management would be able to enhance the quality of life in the elderly people with depression. The present study is an attempt to rapidly assess the depression among elderly living in the urban slum area utilizing the standard short form geriatric depression scale. The results were analyzed to establish relationship of depression if any with physical health status.

Material and Methods

A cross-sectional study was carried out in urban field practice area of a medical college in pune. The total population of the area was 6200. House to house survey was carried out to get the list of people with 60 yrs and above. A total of 270 geriatric study participants were found out of which information was gathered for 254 subjects. Remaining 16 were not available in the house even after repeated attempts of house visits during the survey period. Data pertaining to demographic profile, personal details and short form geriatric depression scale questionnaire details were collected through individual private interviews. Individuals with scores less than 5 were designated as normal and those with scores ≥ 5 were diagnosed to be suffering from depression[7]. A thorough physical examination has been carried out to detect the presence of chronic diseases like

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hypertension, diabetes mellitus and refractive defects.

Results

Among the 254 study participants, 73(29%) were having signs of depression and 181 (71%) were without depression (Fig 1). The demographic and socio-economic profile of both these groups is shown in Table I. The demographic profile of age and sex showed equal affection of depression among the elderly. Other factors like socio-economic status, living in a joint or nuclear family and the status of spouse presence also showed equal preponderance. The difference in the number of people of affected with depression in all the above categories showed no statistical significance. However, factors like self health perception and history of hospitalization in the previous 1 year showed statistically significant difference

Table I: Comparison of demographic and socio-economic profiles between those suffering with or without depression.

	Number of elderly suffering from Depression			
	Yes (%)	No(%)		
Men	15	43		
Women	58	138		
Age <70 years	43	101	1.14 (0.63 – 2.04)	NS
>70 years	30	80		
Spouse living	35	96		
Living alone	38	85		
Living in a Joint Family	36	106	0.69 (0.38 – 1.23)	NS
Living in Nuclear Family	37	75		
SE Status				
Low	16	42	0.93 (0.46 – 1.87)	NS
Middle	57	139		
Self Health Perception			9.40	
Good	50	34	(4.85 –	P<0.05
Bad	23	147	18.36)	
Hospital Admission within last1 year			2.50	
Present	11	12	(0.97 – 6.44)	P<0.05
Absent	62	169		

The relationship of physical ill-health (Low vision, Diabetes and hypertension) with psychological depression is shown in Table II. Visual acuity at the time of survey is correlated with the detection of depression among the elderly. Seventy three people were found to be suffering from depression. When analyzed for visual acuity status psychological status of depression showed significant association with low vision. Similarly diabetes with or without hypertension also showed statistically significant association (Odds Ratio: 6.27 CI=1.22 – 43.09). Presence of hypertension showed no significant relationship with depression.

Table 2: Relation of chronic diseases and Depression among study participants

		Number of elderly suffering from Depression			
		Yes (%)	No (%)		
1	Vision Low (Less than 6/18)	42	79	1.75 (0.97 - 3.15)	P<0.05
	Normal Vision (More than 6/18)	31	102		
2	Hypertension (>140 Systolic/or >90Diastolic)	25	58	1.10 (0.60 – 2.04)	NS
	(<140 Systolic/or <90Diastolic)	48	123		
3	Diabetes (Fasting BS > 126)	23	9	8.92 (3.64 – 22.39)	P<0.001
	(Fasting BS < 126)	49	171		
4	Diabetes & Hypertension Present	10	2	6.27 (1.22 – 43.09)	P<0.001
	Absent	63	79		

Discussion

The present study finding of 29% prevalence of depression among elderly aged ≥ 60 years coincides with the reports from other parts of India and Maharashtra[1]. This study also brings out the lack of gender difference for depression among the elderly living in urban slum[8]. Earlier studies showed female predilection for psychological disorders like depression among elderly in general[9]. However, compulsion for work and equal occupational status among urban area might be responsible for equal affection of depression[10].

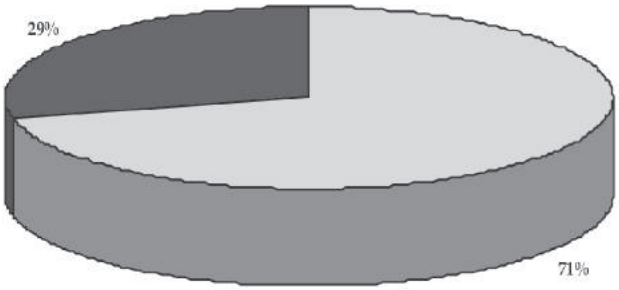
Unlike earlier reports, depression was not found to be associated with marital status. This finding suggests that urban elderly psychological status is not being influenced by the marital status and/ living alone or in a joint family. Engagement in occupation for livelihood and financial independence might be responsible for this finding.

When analyzed for self perception of health status, it was found that those who assess their health as bad were found to be suffering more from depression compared to those who feel good about their health status. Earlier reports also suggested that depression to be strongly associated with self feelings[11], this finding is significant. Previous hospitalizations indicate poor health is associated with depression. Individuals with poor

health/ previous hospitalizations were more prone to suffer from psychological disorders like depression.

The relationship of diabetes, low vision and diabetes with hypertension showed significant association with depression. Hypertension alone is not associated with psychological status as disease per se is symptomless in majority of the cases[12]. Diabetes and low vision being interfering with routine daily activities were found to be associated with psychological state of depression[1,11]

Fig 1. Status of Depression among study participants



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ORIGINAL ARTICLE

Ventilator-associated Pneumonia due to Multidrug Resistant Organisms in Medical Critical Care Unit of Tertiary Care Teaching Hospital from Western India- a cause for concern

Neeta P. Jangale & Ritesh Shirpurkar
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ABSTRACT

Ventilator-associated pneumonia (VAP) is most common nosocomial infection reported among mechanically ventilated intensive care unit patients. Multidrug resistance is being increasingly reported among Pseudomonas aeruginosa and other gram negative bacilli especially from intensive care unit patients, posing great difficulties in their management. We studied the incidence of VAP and bacterial profile with sensitivity in medical critical care unit. Endotracheal aspirates were subjected to quantitative culture. The incidence of VAP was 32.81%. Pseudomonas aeruginosa and Acinetobacter species were most common isolates. More than 65% of Pseudomonas aeruginosa showed resistance to all aminoglycosides tested and more than 50% were resistant to cephalosporins with anti-pseudomonal activity. Periodic circulation of susceptibility pattern of VAP pathogens to clinicians would be important for reducing multidrug resistance.

Keywords: endotracheal aspirate, multidrug resistance, VAP

Introduction

Ventilator-associated pneumonia (VAP) remains an important cause of mortality and morbidity despite the introduction of potent broad spectrum antimicrobial agents, complex supportive care modalities and use of preventive measures. Furthermore the increased mortality rates have been shown to be associated with aerobic gram negative bacteria (especially Pseudomonas aeruginosa, Acinetobacter species) and medical rather than surgical illness.[1,2,3] Laboratory identification of microbial cause is important for in the absence of such identification, antimicrobial therapy may not be optimal. Several studies have shown that appropriate antimicrobial treatment of patients with VAP significantly improves the outcome.[4,5,6] Therefore, VAP associated flora and its susceptibility pattern needs to be studied in each setting. In view of relative paucity of recent epidemiologic data on the exact incidence of VAP, its bacterial profile and the antibiotic susceptibility of pathogens in our medical CCU, the present project was undertaken. This would provide useful information to guide clinicians in their choice of therapy and to contribute to the institutional picture of antimicrobial resistance.

Material And Methods

Patient selection:

The present study was undertaken in an urban tertiary care teaching hospital over a period of one year. This hospital has 10 bedded medical critical care unit (CCU). A total of 240 patients were admitted to the medical CCU during the study period. Patients with more than 48 hours of mechanical ventilation were included in the study. Patients who were on mechanical ventilation (MV) for less than 48 hours or developed pneumonia within first 48 hours were excluded from the study. Also patients with acute pulmonary diseases such as acute respiratory distress syndrome, fulminant pneumonia and pulmonary edema were excluded from the study. A patient was labeled as a case of VAP if there was a new or progressive pulmonary infiltrate on chest X- ray, a colony count above the threshold of 10^5 cfu/ml on quantitative culture of endotracheal aspirate in addition

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to at least two of the following: temperature > 38 ^{0}C/ leucocytosis > 10,000 per cmm or leucopenia < 4000 per cmm / presence of purulent respiratory secretions.

A total of 64 patients on MV for more than 48 hrs who fulfilled the inclusion criteria were followed up prospectively. The development of first episode and the subsequent episodes of VAP was recorded. The end point was removal of patient from ventilation or death.

Procedure of ETA collection:

ETA samples were obtained twice a week. A sterile mucus extractor (trap) was used to collect the sample under all aseptic precautions. The extractor is provided with a two way port, one end of which is attached to the suction and the other to the endotracheal or tracheostomy tube. On suctioning sample gets collected in the extractor. If the secretions were very scanty or thick, the patient was given nebulization (N- acetyl-cysteine) and after 15 minutes the sample was collected. The mucus extractor was transported to the microbiology laboratory within 1 hour.

Microbiological processing & Method of quantitative analysis:

The sample was homogenized using dithiothreitol (dTT, HIMedia), a mucolytic agent. Two smears were prepared and subjected to Gram and rapid Geimsa staining. Geimsa stained smears were examined under high power objective(X400).Semi-quantitative grading of polymorphonuclear neutrophils(PMN) was done by using categories +, ++, +++ corresponding to 0-10,11-20,21 or more PMN/high-power field respectively. The findings were recorded A 10^3 dilution of homogenized ETA was prepared in sterile saline. Blood agar, chocolate agar, MacConkey's agar and Sabouraud's dextrose agar were inoculated. The diagnostic threshold for ETA quantitative culture was taken as 10^5 cfu/ml. Growth below the threshold was assumed to be due to colonization or contamination. [8,12].

Identification of organisms was done to the species level following standard microbiological methods and antibiotic susceptibility testing was done by modified Kirby- Bauer disc diffusion method. All isolates of enteric gram negative bacilli (EGNB) were tested for extended spectrum beta-lactamase (ESBL) production by NCCLS phenotypic screening test (double disc diffusion method) and all isolates of Staphylococcus aureus were tested for methicillin resistance using 1µg oxacillin disc.

Results

During study period a total of 240 patients were admitted to the medical CCU, of which 64 were on mechanical ventilation for >48 hrs and 21 developed VAP. The incidence of VAP was observed to be 32.81%. Of the 21 patients, 11 (52.38%) had single episode of pneumonia while 10 patients i. e. 47.62% had multiple episodes of VAP. In 71.42% patients Geimsa staining showed PMN grading more than > 21 PC/HPF as well as bacteria on gram staining.

Total 57 isolates were obtained. The most frequent etiologic agents found were Pseudomonas aeruginosa (38.59%) and Acinetobacter species (29.82%) while enterobacteriaceae group of organisms made up 24.56%. Staphylococcus aureus constituted 7.03% of total isolates. Fungal pathogen was not recovered from any patient. In 21 patients diagnosed as VAP cases, 13 patients had monomicrobial infection and 8 patients polymicrobial infection. It was observed that Pseudomonas aeruginosa and Acinetobacter spp were 100% resistant to gentamycin. Piperacillin/tazobactam and meropenem were found to be most effective antibiotics against Pseudomonas aeruginosa. Though all Staphylococcus aureus strains were methicillin resistant, none was resistant to vancomycin and linezolid.

Table1 : Isolation frequency of VAP agents

Species / Strain	NO.	Percentage
Ps. aeruginosa	22	38.50
Acinetobacter spp	17	29.82
Citrobacter species	07	12.28
Klebsiella species	04	7.01
Escherichia coli	01	1.75
Proteus species	02	3.50
Staph. aureus	04	7.01

Discussion

VAP is the commonest nosocomial infection amongst patients receiving MV in CCU. It is caused by wide range of organisms.[12,13,14,15,16, 17]. The increasing antimicrobial resistance of bacterial pathogens associated with VAP has made its treatment difficult.[18]

In view of this, present study was undertaken to determine the incidence of VAP, distribution of pathogens and their antibiotic susceptibility pattern.

Fig 1 - Mucus Trap Being Connected to Tracheostomy Tube

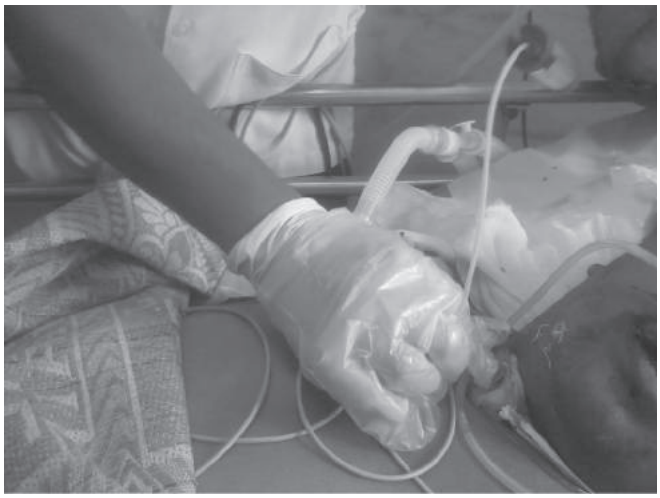


Fig 2-Mucus Trap Disconnected from Suction Machine

Table 2: Antibiotic Susceptibility of VAP pathogens
(Gram Negative Organisms - total 53 isolates)

Antibiotic	Ps. aeruginosa (n=22)	Acinetobacter spp (n=17)	EGNB* (n=14)
Ampicillin	-	17(100%)	14(100%)
Piperacillin	17(77.27%)	15(88.23%)	13(92.85%)
Gentamycin	22(100%)	17(100%)	13(92.85%)
Amikacin	15(68.18%)	8(36.36%)	8(57.14%)
Tobramycin	19(86.36%)	15(88.23%)	11(78.57%)
Kanamycin	-	16(94.11%)	11(78.57%)
Cephalothin	-	16(94.11%)	14(100%)
Cefuroxime	-	14(82.35%)	11(78.57%)
Cefoperazone	13(59.09%)	-	-
Cefotaxime	-	14(82.35%)	4(28.57%)
Ceftazidime	15(68.18%)	-	-
Cefepime	13(59.09%)	10(58.82%)	4(28.57%)
Ciprofloxacin	15(68.18%)	8(47.05%)	9(64.28%)
Ampicillin Sulbactum	-	6(35.29%)	6(42.85%)
Piperacillin tazobactum	4(18.18%)	-	-
Meropenem	8(36.36%)	10(58.82%)	4(28.57%)

*EGNB= enteric gram negative bacilli i.e. Citrobacter, Klebsiella, Esch coli, Proteus spp
Noted strains of Staph. aureus were isolated thus making total 57(22+17+14+4) isolates

Fig 3 - Tracheal Secretion Sample in Tube

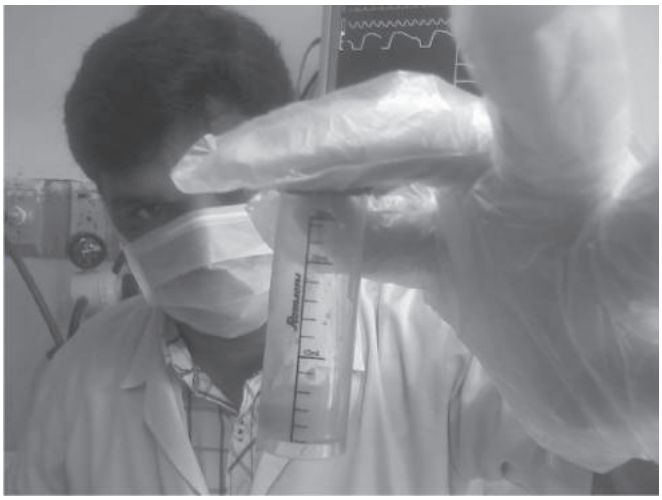
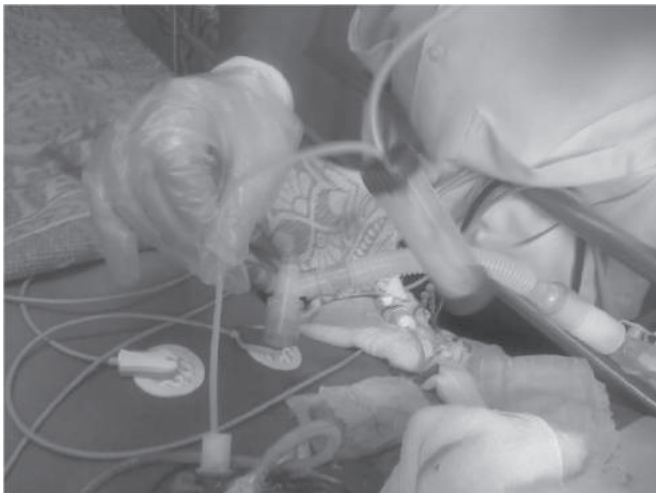


Fig 4 - Suctioning of Secretions



The incidence of VAP as reported by various workers varies from 9% to 68.18%.[12,13,15,16, 19,20,21] This is due to diverse study designs, different methods of specimen collection and differing diagnostic methodologies. In the present study, incidence of VAP was found to be 32.81% which is an alarming situation. It has been demonstrated that if standard guidelines aimed at reducing cases of VAP if followed appropriately, result in effective reduction of the VAP rate.[22]

Laboratory identification of microbial cause is important for optimal antimicrobial therapy. Even the simple microscopic examination gives vital information. Salata et al reported that EA specimens from intubated patients with pneumonia showed higher semiquantitative grading of neutrophils and bacteria [23].

The present study findings revealed significant difference in presence of bacteria on gram stain and higher number of polymorphs in VAP and non VAP cases (71.42% as against 13.88% of non-vap cases-p < 0.000001). Thus in more than two third of cases simple microscopic examination of ETA would predict VAP.

The specific microbial causes of VAP are many and distribution of microorganisms differs according to the patient population under study (i.e. surgical/ medical/ trauma), duration of hospital and ICU stay and the duration of mechanical ventilation. A baumannii was found to be the most common pathogen in VAP in Malaysia, Pakistan, India.[17]

Even in the present study Pseudomonas aeruginosa and Acinetobacter species were the most common offending organisms; both of which are potentially drug resistant. Similar pathogen profile was reported by many.[23,22,24]

Multidrug resistant organisms in VAP have been reported by some workers.[22] The incidence of multi-resistant organisms is closely related to many factors , important amongst them being prophylactic antibiotic therapy. Fagon et al showed that in patients who had received prior antibiotics, the rate of VAP caused by Pseudomonas aeruginosa, Acinetobacter species and MRSA was higher.[13] Talon et al reported previous use of third generation cephalosporin as a significant predictor of infection with Pseudomonas aeruginosa. [18] The predominance of Pseudomonas aeruginosa and Acinetobacter species in VAP cases in the present study might be due to the fact that the patients on ventilation were administered a combination of third generation cephalosporin (cefotaxime/ ceftazidime/ ceftriaxone) and metronidazole prophylactically. Therefore it is essential that clinicians are aware about resistance pattern of common organisms responsible for VAP in their setting to avoid administration of nonspecific antimicrobials.

Various studies have shown that as much as 50% of antibiotic use is inappropriate.[25,26]Inappropriate therapy contributes to emergence of resistant organisms. Moreover inappropriate therapy is a major risk factor for excess mortality in VAP patients in the ICU. [27] Mohanasoundaram has observed the high resistance related to the increased use of broad spectrum antibiotics. [28] He found that multidrug resistant P.aeruginosa is on the rise especially in nosocomial infections and concluded that rigorous monitoring of MDR in P.aeruginosa, restriction of the inappropriate use of antimicrobial agents and adherence of infection control practices should be emphasized to delay the emergence of clinically significant P.aeruginosa. According to Nseir admission to an ICU room previously occupied by a patient with MDR P. aeruginosa or A. baumannii is an independent risk factor for acquisition of these bacteria by subsequent room occupants. [29]

In the present study, Pseudomonas aeruginosa , which was the predominant isolate, showed a high degree of resistance against various groups of antibiotics. Isolates were highly resistant to gentamycin (100%) and tobramycin (86.36%). A high degree of resistance was observed against piperacillin(77.27%), followed by ciprofloxacin and ceftazidime(68.18%) and cefpime and cefoperazone(59.01%).Of the aminoglycosides, amikacin was the most effective drug, but even it had a 68.18% resistance. Only piperacillin/tazobactum and meropenem showed a good efficacy. Overall 27.27% strains were multidrug resistant (resistant to piperacillin, gentamycin, ceftazidime and meropenem) . Although Acinetobacter spp. are generally less virulent than Pseudomonas aeruginosa, these have become problem pathogens because of increasing resistance to commonly used antimicrobial agents[20]. In our study Acinetobacter species showed 100% resistance to ampicillin and gentamycin while high degree of resistance was observed for tobramycin(88.23%), piperacillin (88.23%), kanamycin and cephalothin (94.11% each). However better susceptibility against cefepime was noticed. Ampicillin / sulbactum was the most effective drug (35.29%). This high degree of resistance against many of the antibiotics displayed by Pseudomonas aeruginosa and Acinetobacter species isolates may be due to prior administration of broad spectrum antibiotics (3rd generation cephalosporins in our study) leading to selection of highly resistant strains for the initial colonization of respiratory tract in MV patients.

In the present study, EGNB showed 100% resistance to ampicillin and cephalothin. while ampicillin/ sulbactum, meropenem, cefiperazone, cefotaxime and cefepime were the most effective drugs but none was extended spectrum beta lactamase (ESBL) producer. Therefore, use of appropriate antibiotics directed towards the most prevalent organism shall not only reduce the emergence

of resistant strains but also improve the cure rate and survival.

Conclusion

This study highlighted high incidence of VAP in our setup. Pseudomonas aeruginosa and Acinetobacter species are the main culprits. The causative organisms exhibited high drug resistance. Therefore it is essential to perform quantitative ETA culture with antibiotic susceptibility test for VAP diagnosis. This will lead to appropriate antimicrobial treatment and better outcome. In our view, endotracheal specimens obtained by suctioning and collected in mucus traps represent specimens that are easily obtainable and uncontaminated. Also, microscopic analysis of ETA is of potential use in the empiric selection of antimicrobial therapy.

We believe that our study findings will help in initial prophylactic treatment planning for mechanically ventilated patients in our medical CCU setup and should form a basis for empirical antibiotic therapy in critical patients. Periodic circulation of susceptibility pattern of pathogens to clinicians is an important step in understanding of local epidemiology which can facilitate optimal treatment choices and be beneficial to fight against these multidrug resistant pathogens. Nevertheless, to minimize the risk of bacterial pathogens being acquired via transmission by health-care workers from environmental surfaces or from other patients, hand-washing protocol should be followed meticulously in Critical Care Units

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ORIGINAL ARTICLE

Dual Innervation Of Human Brachialis Muscle

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ABSTRACT

Brachialis muscle anatomy and its innervation has been studied previously by many authors. There have been inconsistent description of the brachialis muscle anatomy in literature. In the present study 40 upper limbs of twenty embalmed Indian cadavers were dissected and found that all specimens of the brachialis had 2 heads, superficial and deep. The larger, superficial head had more proximal origin and distal insertion than deep head. In all specimens, brachialis was supplied by musculocutaneous nerve while only 70% (28/40) cases rceived branch from radial nerve. All specimens of superficial head and 20% (8/40) specimens of deep head were supplied by branches from musculocutaneous nerve entering in their upper third part only. Branches from the radial nerve were observed to enter in 5% (2/40) specimens of superficial head in upper third part and 65% (26/40) specimens of deep head in lower two-third part. These anatomical facts have implications for humeral surgery including both anterior and anterolateral approaches.

Keywords: brachialis, radial nerve, cadaver, musculocutaneous nerve

Introduction

Attachment of human brachials muscle has been investigated by many researchers [1,2] showing the consistent presence of superficial and deep heads in the brachialis with anatomical dissection and /or M.R.I. techniques. Above all, many anatomy students usually has question about the prensence of a well defined sepration plane in the bulk of muscle as text books [3,4] describes presence of 2 heads in brachialis as a variation and not a regular feature .

Innervation of the brachialis too is a long running controversy as most of the authors have considered the musculocutaneous nerve to be the sole motor supply or thought the radial nerve contribution entirely sensory. While some workers [5,6,7,8] have claimed radial nerve supply to be motor also in function by observing contraction in a part of the brachialis muscle in a patient with completely severed musculocutaneous nerve after giving intra operative stimulation. The reported incidences of radial nerve innervations to brachialis has varied from 67% to 100 % by different workers in different populatios [8,6,9,10] . Although detailed anatomy of radial supply to brachialis is widely described in literature, but the information on the distribution of radial and musculocutaneous nerve within the muscle in reference to the presence of superficial and deep heads in brachialis remains inconclusive. In the present study an attempt has been made to describe gross morphology and innervation of brachialis muscle in order to refine the current anterior and anterolateral surgical approaches to the humerus around the elbow joint by better understanding of internervous plane.

Materials And Methods

Twenty embalmed cadavers (40 upper limbs) including 11 males and 9 females were dissected on both right and left side. Skin and subcutaneous tissue were removed from the anterior aspect of arm and upper forearm, exposing the muscles. The musculocutaneous nerve was identified in the plane between bicep and brachialis and its branches to the brachialis were recorded. The radial nerve was then cleaned to see its course from the posterior to anterior compartment of the arm and any branch(es) to the brachialis muscle were noted. The brachialis muscle was completely visualized during dissection, and its length was visually divided into three equal segments to allow comparision with previous studies [6] . The segment into which branches from radial and musculocutaneous nerve entered was recorded. We carefully followed each subdivisuion from radial and musculocutaneous nerve into the brachialis as far as possible by teasing the muscle fibers away from the

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branches usuing forceps and scalpel. We also noted the course of the branches after they arose from the main trunk. For each arm, a tape measure was used to measure the distance from the tip of the acromion process to the proximal part of the tip of the lateral epicondyle of the humerus. Measurements of the total length of the brachialis muscle and length of its extramuscular tendinous part were expressed as a percentage of the distance between the lateral epicondyle and acromion. Histological sections were made of 5 branches of the radial nerve to brachialis to confirm the presence of nerve tissue.

Results

(1) Gross morphology of brachialis

Brachialis muscle was seen uniformly to be consisting of 2 heads, superficial and deep (Figure.1). The superficial head forming the main bulk of the muscle originated

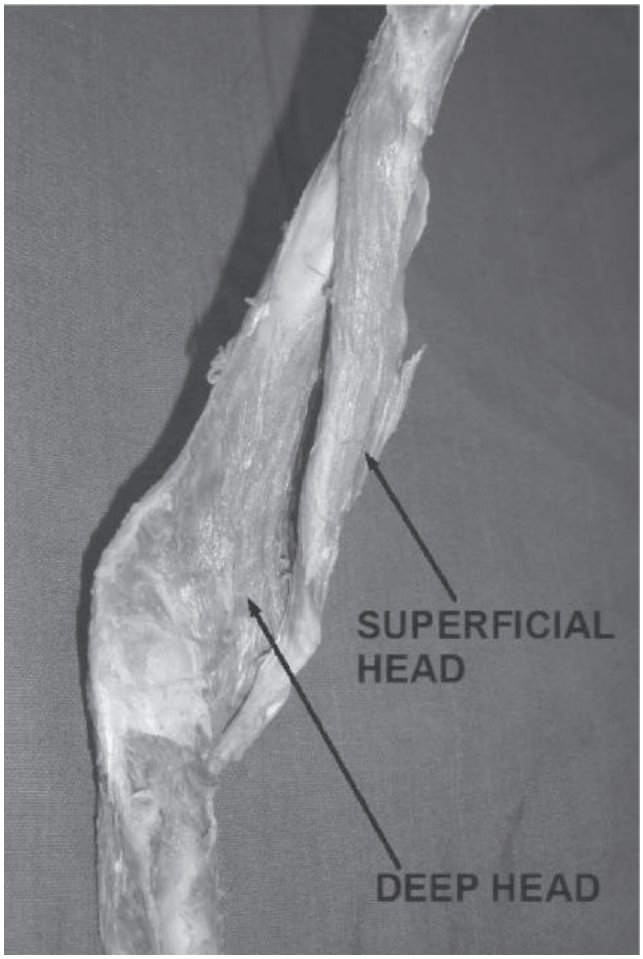

Fig.1 Lateral view of the arm and elbow, showing superficial and deep head of brachialis muscle

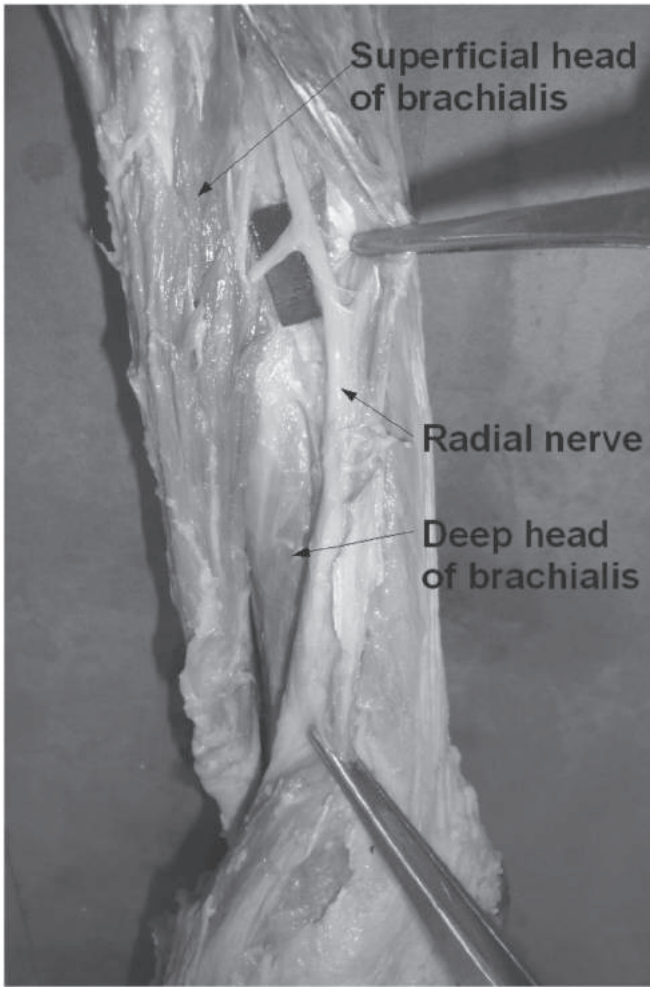

Fig.2 Radial nerve branch entering into the superficial head of brachialis muscle

from the anteromedial and anterolateral surface of the middle third of humerus, embracing the deltoid insertion. In addition it also had attachement to the adjoining part of the lateral intermuscular septum. Its fibers ran vertically and terminated in a thick tendon to be inserted onto the ulnar tuberosity. Fibers of the deep head could be seen arising from the anterormedial and anterorlateral suaface of the distal third of the humerus. In addition fibers were seen to be attached to the medial and lateral intermuscular septum. Fibers of the deep head coming from anterolateral surface ran obliquely across the elbow joint crossing from lateral to medial side. Some of these fibers invaginated the tendon of the superficial head and rest converged to form a thickened aponeurosis with the vertically running fibers of the deep head (coming from anterior-medial surface) to be inserted on to the medial side of the coronoid process. There was no direct muscular attachment of brachialis to

anterior surface of elbow joint capsule. The mean of the total length of the superficial head of the muscle as a percentage of the distance between lateral epicondyle and acromian process was 67.13% (range 60 -72%) and for deep head was 28% (range 22-34%).The mean length of the extramuscular tendon as a percentage of distance between lateral epicondyle to acromion process for superficial head was 54.9% (range 50-56.7%) and for deep head was 22.75% (range 18-28%).

(2) The supply to brachialis from musculo cutaneous nerve

All specimens of superficial head and 20% (8/40) specimens of deep head were supplied by branches having escending course from musculocutaneous nerve in their upper third part only. In 27.5% (11/40) specimen musculocutaneous nervewas seen to give 2 primary branches and in 72.5%(29/40) only single primary branch was observed. Intramuscularly the musculocutaneous nerve divided into branches and approaches toward the middle third and lateral portion of brachialis. A variable number of these branches entered the deep head at its upper third and in the approximate midline crossing the interval between 2 heads.

(3) The supply to brachialis from radial nerve

70% (28/40) specimens of brachialis were innervated by a branch from the radial nerve. These branches from the radial nerve were observed to enter in 5% (2/40) specimens of superficial head and 65% (26/40) specimens of deep head. In all specimens, radial nerve was seen to give a single primary branch to brachialis, which had descending course in 10.7% (3/28) cases, straight in 82.14% (23/28) cases and recurrent or ascending course in 7.14% (2/28) cases. In all the specimens its entry into the superficial head was in upper third only, while in case of deep head in 78.57% (22/28) specimens it entered in middle third and in 14.2% (4/28) specimen into its lower third.(table.1) After entering the muscle these branches ran for a short and relatively transverse course. Regarding all the parameters that we studied, there were no statistically significant differences between male and female cadavers or between the right and left side.

Discussion

Our findings suggest that brachialis muscle uniformly consists of 2 heads, superficial and deep. Which is

Contributing nerve	Number of primary branches		Course	Site of entry into brachialis muscle					
	1	2		Upper third		Middle third			
				S.H.	D.H.	S.H.	D.H.		D.H.
Musculocutaneous nerve (100% of cases)	80 % (32/40)	20% (8/40)	Descending 100% (40/40)	100% (40/40)	20% (8/40)			Lower third S.H.	
			(1)Ascending-7.14%(2/28)						
Radial nerve (70% of cases)	100% (28/28)		(2)Striaght-82.14%%(23/28)	7.14% (2/28)			78.57 % (22/28)		14.2 % (4/28)
			(3)Descending -10.7%(3/28)						

Table1.Innervation pattern of radial and musculocutaneous nerve to brachialis muscle (S.H.-Superficial head, D.H.-Deep head)

described in many of the anatomical text books as a variation only. Whereas it goes in favour of 2 previous studies of Leonello et al.,2007 and Hatice Tuba Sanel, 2009 [2,1] . In the present study, our finding of no direct muscular attachment of brachialis with the capsule of elbow joint conurrs with Hatice Tuba Sanel, 2009 [1]. Eventhough Leonello et.al.2007 reported to have noticed such atteacment and termed it as "articularis cubitus" [2]. The differing morphology of these 2 heads indicates that they may have different developmental origins, nerve supply and function. Embryological basis for double innervations of the brachialis muscle by branches from musculocutaneous nerve and radial nerve in 70% (28/40) specimens can be explained by union of hypomere (flexor) and epimere (extensor) muscle masses derived from two different embryonic muscular primordial [6]. In the remaining muscles (30%) specimens, the brachialis must have been contributed to, solely by the ventral muscle mass which is innervated by the musculocutaneous nerve only. We observed that superficial head was pierced by musculocutaneous nerve in all cases and by radial nerve in 5% (2/40) cases in upper third part (Figure.2). In contrast, Leonello et.al.

reported no radial supply to the superficial head [2] . Our findings of 70% dual innervation in 40 limbs in Indians differs from t he 100% incidence of 16 limbs reported by Ip and Chang in Chinese population [8] , 81.6% cases of 152 limbs by Mahakkanukrauh (2002) in Thai cadavers [6] and 67%cases of 42 limbs by Blackburn et .al.(2007) in Caucasians[9] but resembles to 72.24% by Prakesh et.al. (2009) in 80 Indian cadavers [10]. It may reflect a difference in the sample size or ethnic differences.

Exhaustive study of literature did not yield any functional aspect of 2 heads of brachialis muscle even though Leonello et. al. claims that the deep head is more important for the initiation of flexion from full extension and the superficial l head provides greater power once the elbow is flexed [2]. The possible reason of 25% (7/28) incidences of recurrent or ascending branch from the radial nerve in our study to the brachialis may be due to differential growth of the lateral intermuscular septum such that the radial nerve was pulled distally and a branch arising from it tosupply brachialis had to recur.

In conclusion, this study has shown that territory of radial innervation for deep head includes its middle and lower third along the lateral margin. While twigs from musculocutaneous nerve passed upto the middle third and lateral portion in all cases of superficial head & 20% cases of deep head, and the variable number of the terminal branches from musculocutaneous nerve cross the intermuscular plane in its upper third part only. Hence lower part of this plane of sepration between two heads could be used in the approaches to hkumerus .The lower two-third fibers of deep head in lateral portion getting supply from radial nerve could then be split from the remaining fibers of deep head (innervated by musculocutaneous nerve) to minimize denervation of the muscle.

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ORIGINAL ARTICLE

Role Of Inj. Ropivacaine (0.2%) In Tea For Opcab

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ABSTRACT

Background: Thoracic epidural anaesthesia (TEA) has gained in popularity in cardiac surgery over the last decade. Till date, the anaesthetic – analgesic effects of 0.2% epidural Ropivacaine in off-pump coronary artery bypass surgery (OPCAB) have been proved in fewer studies despite its widespread clinical use. In this randomized prospective controlled study, we assessed the efficacy of continuous TEA with 0.2% Ropivacaine on hemodynamics and postoperative analgesia in the perioperative management of OPCAB surgery. **Methods:** Sixty patients undergoing OPCAB were enrolled in this study and randomized to two groups. The GA group (n=30) received Inj. Midazolam (0.1mg/kg) & Inj. Fentanyl (10mcg/kg) for induction. TEA was installed >1 h before application of heparin at levels T5–T6 or T6-T7 in GA+TEA group (n=30). Induction was similar to GA group in GA+TEA group. Analgesia was provided by the epidural infusion of 0.2% Ropivacaine at the rate of 5-7 ml/hr intraoperatively and continued 24 hours in the postoperative period after extubation. **Results:** During OPCAB, TEA decreased HR but maintained arterial pressures and reduced the consumption of Fentanyl and Pancuronium significantly as compared to GA group. In the postoperative period after extubation, the HR, arterial pressures and CVP were maintained as pain control was very good in GA+TEA group. There was no neurological complication related to TEA in this study. **Conclusions:** We conclude that TEA using 0.2% Ropivacaine along with GA improves hemodynamic control during and after OPCAB surgery, significantly reduces the intraoperative anaesthetic drug requirement and more effective in postoperative pain control.

Keywords: Ropivacaine, Thoracic epidural analgesia, OPCAB

Introduction

Coronary Artery Bypass Grafting (CABG) surgery is a common procedure performed to improve blood flow to heart in patients with ischemic heart disease. Until recently CABG surgeries were performed using general anaesthesia. Thoracic epidural anaesthesia (TEA) has gained in popularity in cardiac surgery over the last decade. Till date, various combinations of local anaesthetics and / or opioids have been used in the TEA in on pump CABG and in off pump CABG surgeries. [1]-[3]

But the anaesthetic – analgesic effects of 0.2% epidural Ropivacaine in OPCAB have been proved in fewer studies, despite its widespread clinical use. [4]-[6]

TEA for CABG blocks the cardiac sympathetic fibers which provides good protection from stress response, [7] ensures hemodynamic stability, allows early extubation, [8] improves distribution of coronary blood flow, [9] & provides effective pain relief. [10],[11]

Ropivacaine, a new member of the long acting amino amide class of local anaesthetics, is closely related to the chemical structure of Bupivacaine. It has both analgesic & anaesthetic effects. Ropivacaine and Bupivacaine are comparable in pharmacokinetic properties and the onset and duration of sensory block. However, the frequency, degree, and the duration of motor block are less affected by Ropivacaine than Bupivacaine when compared in same concentration. This property is useful in OPCAB surgeries which do not require muscle paralysis for surgical exploration. From both animal and human studies, there is some evidence that Ropivacaine has lower cardiovascular and central nervous system toxicity than Bupivacaine. [12],[13]

Therefore, we conducted a prospective randomized clinical study to evaluate the potential benefits of continuous TEA using 0.2% Ropivacaine on hemodynamics as primary aim, while intraoperative requirement of amount of narcotic drugs, muscle relaxants and postoperative analgesia as secondary aims in the perioperative management of OPCAB surgery.

Methodology

Study design: Prospective, single centered, randomized interventional controlled study done on a group consisting of 60 patients. Inclusion criteria: Patients in the age group of 35 to 75 years, selected for elective bypass grafting surgeries with stable angina, left

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ventricular EF >30%, platelet counts >1,00,000/ml , INR <1.5, last dose of Tab. Clopidogrel intake >7 days before scheduled date of surgery. Exclusion criteria: Urgent or emergency procedure, requirement of inotropic drugs, acute MI in previous 7 days, unstable angina, clinically significant associated valvular disease, general contraindications for epidural technique, insertion of the epidural catheter requiring more than 2 attempts or 'bloody tap' for >one time, pregnancy.

Institutional and review boards approved the investigation. All patients included in study were explained about the nature of study & a written informed valid consent on separate consent form was taken from each patient on the night prior to the scheduled date of surgery. All queries from patients were cleared.

Study procedure:

Patients submitted to OPCAB were randomly allocated to following groups before surgery

Group GA – received GA

Group GA+TEA – received GA + perioperative TEA

ACE-inhibitors were suspended on the day before surgery. Calcium-channel antagonists and ß-adrenergic blocking drugs were continued until the morning of surgery. After taking the patient inside operation theater, routine monitors – pulseoximeter, five lead electrocardiograph, and NIBP – were attached. Baseline heart rate (HR), blood pressure (BP), electrocardiogram (lead II & V5 monitoring) was recorded.

Group GA:

Radial artery cannulation for invasive BP monitoring & central venous cannulation for central venous pressure (CVP) measurement were inserted under local anaesthesia.

GA was induced with Inj. Midazolam (0.1mg/kg), Inj. Fentanyl (10mcg/kg) & Inj. Rocuronium (0.9mg/kg). Tracheal intubation was done with appropriate number of endotracheal tube. GA was maintained with Sevoflurane (0.6% -1%)-Nitrous oxide-Oxygen gas mixture. Further doses of Inj. Pancuronium (0.02mg/kg) was given only after analyzing the muscle contraction with the help of Peripheral Nerve Stimulator instrument even after Train of Four (TOF) ratio is 0.25% & Respiratory Gas Monitor to maintain the expired gas concentration (Sevoflurane) between 0.4% to 0.6%. Patient was kept on Intermittent Positive Pressure Ventilation to maintain an end tidal CO2 of 30-35 mm Hg.

Group GA+TEA:

Patients randomized to GA+TEA group had an epidural catheter inserted 1 hour prior to starting of Injection Heparin. The catheter was inserted at T5-T6 or T6-7 level using 16 gauge needle, by a midline approach in sitting position. The insertion was performed in less than 3 attempts & by loss-of-resistance-saline technique. The epidural procedure was considered as failure if the insertion technique required more than 2 attempts or 'bloody tap' for >one time. In the event of 'bloody tap', a higher level was attempted for epidural placement. The placement of the catheter in the correct space was checked by test dose of 2 cc of 2% Inj. Lignocaine through the epidural catheter. Patient was then given supine position. Radial artery & central venous cannulation was done under local anaesthesia.

Epidural block was established by 8-10 ml of Inj. Ropivacaine (0.2%). The block assessment was done 20 mins later by using loss of temperature sensation to cold bilaterally at the midclavicular line with ether swab. Successful block was defined as block over T1 to T8 dermatomes. If required, block was extended with 2 ml of 0.2% Ropivacaine. Failure to obtain such a block was considered as failure of epidural technique & the patient was transferred to only GA group. Epidural catheter was removed after 24 hours of extubation, ensuring 4 hours heparin free interval, as per institutional protocol.

General anaesthesia was induced and maintained similar to GA group. As soon as the patient was hemodynamically stable, the epidural infusion of 0.2% Ropivacaine was started at the rate of 5-7 ml/hr and was kept stable during the surgery.

All patients included in the study were operated with median sternotomy surgical approach. Unfractionated Heparin 200 IU /kg was given 3 minutes before starting anastomosis for all patients & at least 1 hour after epidural catheter placement to accomplish an activated clotting time (ACT) of 250- 350 seconds & antagonized using Inj. Protamine 1 mg for each 100 IU of Heparin after completion of anastomosis to return the ACT to baseline or less than 120 seconds.

Intraoperative hemodynamic management was standardized to represent routine practice, although, certain acceptable limits were defined to optimize individual patient management.

- Hypotension (systolic BP<20% of lower limit of normal range) was treated with volume or vasopressors or inotropes, depending on the CVP levels.
- Hypertension (systolic BP>20% of upper limit of normal range) was treated with Inj. Propofol (0.25-1mg/kg), a volatile agent or Glyceryl trinitrate.
- Tachycardia (HR >100 beats/min) was treated with beta – adrenergic blocker.
- Bradycardia (HR <40 beats/min) was treated with anticholinergics.

The patient characteristics (age, weight, and sex), preoperative medical status, and left ventricular function as well as operative data (number of grafts, haemodynamics), any complications and time to extubation of all patients were recorded. Hemodynamic measurements were recorded from induction till patient was extubated & then 2 hourly in the first 8 hours followed by 4 hourly till 24 hrs after extubation. Postoperatively, patient was shifted to ICCU and ventilation was continued with same parameters. The patients were extubated by fast track extubation technique i.e. within 6 hours postoperatively. After extubation the level of sedation was evaluated by the attending physician by means of the Ramsay Sedation Scale (RSS) score 1-6.

Before surgery, the patients were familiarized with Visual Analog Scale to assess their pain. (0= no pain to 100 = maximum imaginable pain).

In the Group GA, once the patient was extubated, the pain relief was given by Inj. Diclofenac 75 mg IV.

In the GA+TEA group, the epidural infusion was commenced as soon as the patient was hemodynamically stable after shifting in the ICU, & was continued only till 24 hours after extubation. After extubation, the rate of infusion was titrated according to clinical need. If the patients have pain score > or = 40 on VAS of pain of 0-100 in the thoracic area, epidural rate was increased in increments of 1 ml/hr every 2 hours. The rate was decreased if there was paraesthesia in dermatome C8 or higher in a painless patient. Motor monitoring was performed for upper limb to assess the complications of epidural technique, if any. It was graded as according to Epidural Anaesthesia Scoring Scale for Arm Movements (ESSAM). [14]

Pain rescue medications for the GA group were Inj. Tramadol 50 mg intravenously and for GA + TEA group were Inj. Diclofenac 75 mg intravenously.

Statistical Analysis

Study protocol was discussed with statistician and data was analyzed by Excel and statistical study packages (SPSS software package). Mann Whitney U test was used here as non parametric test for 2 independent samples. The Fisher exact test was used for categorical data. The discrete data were analyzed by two-sided chi-square test and expressed as patient number or percentage. For all tests, a P-value < 0.05 was considered as a statistically significant difference. The group size was calculated to find a 20% difference of mean diastolic or systolic blood pressure 4 h after surgery with a power of 0.8. This difference was defined as being of clinical significance before the study.

Results

There were no significant differences in demographic parameters including ejection fraction, number of grafts, comorbidities, duration of surgery and of mechanical ventilation between the 2 groups.[Table 1]

Table 1 : Patient and group characteristics.

	GA	GA+TEA
Age (years)	59 (38-75)	60 (42-75)
Weight (kg)	64.16 (50-78)	65.23 (50-79)
Sex (M/F)	27/3	25/5
Ejection fraction (%)	53 (7)	54 (6)
Diabetes (%)	53.33	50
Hypertension (%)	40	36.66
Number of grafts (%)	3 (76.67), 2(23.33)	3 (76.67) , 2(23.33)
Duration of Surgery (hrs)	4.50 (4.07-4.69)	4.50 (4.39-5.00)
Duration of mechanical ventilation (hrs)	5.00 (4.53-5.00)	5.00 (4.53-5.00)

Data are presented as mean (range), mean (SD) or

percentage

Both the groups were comparable in baseline parameters with no significant differences in HR, SBP, DBP, MAP & CVP.

The HR response showed significant differences in both the groups during intraoperative period ($P < 0.05$). SBP showed no significant differences during the intraoperative period ($P > 0.05$), while it was maintained towards extubation. DBP and MAP showed no significant differences during induction and intraoperative period extending to the extubation period ($P > 0.05$). [Table 2]

Table 2 – Hemodynamic parameters before extubation

		HR(beats/min)		SBP (mm Hg)		DBP (mm Hg)		MAP (mm Hg)		CVP(cm of H2O)	
Event	Grp	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value
Baseline	GA	66.2 ± 4.11	0.34	112± 5.11	0.20	62.93 ± 6.51	0.67	84.16 ± 8.09	0.83	11.40 ± 1.30	0.46
	GA+ TEA	65.23 ± 3.95		110 ± 4.54		62.33 ± 4.42		83.76 ± 6.19		10.03 ± 1.65	
Induction	GA	76.16 ± 7.18	0.035	112±1 2.07	0.07	66.53 ± 16.0	0.94	832 ± 11.1	0.23	10.53 ± 0.94	0.00
	GA+ TEA	71.90 ± 8.06		107±1 0.68		66.27 ± 9.86		80.00 ± 9.40		9.23 ± 1.57	
Post Induction	GA	77.66 ± 7.80	0.028	110 ± 8.18	0.64	65.50 ± 8.51	0.60	80.43 ± 7.72	0.70	10.50 ± 1.14	0.00
	GA+ TEA	73.03 ± 8.12		109 ± 8.63		66.60 ± 7.44		81.17 ± 7.00		9.40 ± 1.59	
Sternotomy	GA	73.66 ± 7.44	0.23	121 ± 5.32	0.13	70.20 ± 7.18	0.02	87.10 ± 5.63	0.77	11.73 ± 1.86	0.23
	GA+ TEA	71.03 ± 9.55		115±1 9.41		73.77 ± 4.07		87.60 ± 7.22		11.10 ± 2.20	
LIMA Harvest	GA	75.53 ± 5.78	0.004	113 ± 7.10	0.41	66.23 ± 6.30	0.36	81.83 ± 6.19	0.29	10.30 ± 2.31	0.66
	GA+ TEA	70.10 ± 8.18		114 ± 5.26		67.50 ± 4.18		83.20 ± 3.35		10.53 ± 1.72	
LAD	GA	75.50 ± 6.14	<0.001	113 ± 8.21	0.66	65.33 ± 7.17	0.26	81.27 ± 7.28	0.53	11.00 ± 1.26	0.45
	GA+ TEA	67.26 ± 8.53		112 ± 5.41		67.07 ± 4.36		82.20 ± 3.58		10.73 ± 1.46	
RCA	GA	76.60 ±10.88	0.002	110 ± 8.51	0.88	61.73 ± 7.86	0.27	77.87 ± 7.81	0.57	9.83 ± 1.15	0.75
	GA+ TEA	67.03 ± 12.4		109 ± 7.21		80.33 ± 9.83		78.80 ± 4.52		9.97 ± 1.92	
LCx	GA	79.36 ± 11.3	0.001	108 ± 7.24	0.97	63.40 ± 6.90	0.54	78.43 ± 6.71	0.70	10.00 ± 1.23	0.18
	GA+ TEA	68.56 ± 13.0		108 ± 6.32		64.33 ± 4.74		79.00 ± 4.45		9.47 ± 1.76	
Hemostasis	GA	71.20 ± 10.8	0.010	113 ± 8.62	0.70	69.87 ± 8.18	0.01	84.40 ± 6.58	0.02	10.40 ± 1.83	0.00
	GA+ TEA	64.00 ± 9.05		112 ± 8.65		64.87 ± 6.89		80.73 ± 5.57		10.43 ± 1.55	
Closure	GA	67.36 ± 7.94	0.030	116±1 0.61	0.76	68.13 ± 8.84	0.01	84.40 ± 7.21	0.03	9.80 ± 1.61	0.14
	GA+ TEA	62.96 ± 6.89		116±1 2.85		62.63 ± 6.50		80.43 ± 6.68		9.17 ± 1.70	
In ICU till extubation	GA	67.30 ± 11.5	0.41	111 ± 8.39	0.14	68.23 ± 7.09	0.03	82.83 ± 6.80	0.02	10.60 ± 2.33	0.00
	GA+ TEA	65.23 ± 7.46		108 ± 7.42		64.87 ± 4.11		79.57 ± 3.57		10.93 ± 1.76	
Extubation	GA	82.93 ± 15.4	0.04	123±1 3.74	0.00	70.55 ± 2.25	0.42	88.31 ± 12.3	0.71	10.72 ± 2.00	0.26
	GA+ TEA	75.00 ± 13.8		115 ± 6.81		73.17 ± 12.52		87.21 ± 10.1		10.07 ± 2.37	

In the postextubation period, all hemodynamic parameters between 2 Groups showed significant differences ($P < 0.05$) with a significant fall in the GA+TEA Group. [Table 3]

Table 3 – Hemodynamic parameters after extubation

		HR (bpm)		SBP (mm Hg)		DBP (mm Hg)		MAP (mm Hg)		CVP (cm of H2O)	
Time	Group	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value
0 min	GA	84.07 ± 6.70	<0.00 5	119.13 ± 15.8	0.03	75.20 ± 0.54	<0.00 5	89.90 ± 11.6	<0.00 5	11.33 ± 1.18	<0.00 5
	GA+ TEA	75.67 ± 5.62		112.27 ± 5.56		63.33 ± 5.37		79.63 ± 3.75		10.30 ± 1.73	
2 hours	GA	83.47 ± 6.77	<0.00 5	107.93 ± 9.77	0.26	59.80 ± 5.60	<0.00 5	82.50 ± 5.50	<0.00 5	10.50 ± 1.57	<0.00 5
	GA+ TEA	75.30 ± 6.40		104.60 ± 12.5		61.37 ± 5.04		75.77 ± 6.65		9.20 ± 1.42	
4 hours	GA	82.97 ±7.71	<0.00 5	120.60 ± 14.8	0.01	79.27 ± 3.89	<0.00 5	92.97 ± 13.6	<0.00 5	10.07 ± 1.28	<0.00 5
	GA+ TEA	72.60 ± 6.69		112.47 ± 5.66		66.50 ± 5.18		81.83 ± 4.29		9.93 ± 1.48	
6 hours	GA	79.57 ± 7.80	<0.00 5	115.07 ± 10.1	<0.00 5	71.57 ± 9.68	<0.00 5	86.03 ± 9.05	<0.00 5	10.83 ± 1.37	0.05
	GA+ TEA	72.50 ± 8.06		107.33 ± 5.49		64.33 ± 2.87		78.63 ± 2.14		9.90 ± 2.20	
8 hours	GA	82.87 ± 8.58	<0.00 5	109.97 ± 14.0	0.56	68.80 ± 9.88	<0.00 5	82.50 ± 10.2	0.01	11.33 ± 1.65	0.01
	GA+ TEA	77.07 ±7.77		108.27 ± 7.20		61.67 ± 4.00		77.20 ± 4.37		10.03 ± 2.27	
12 hours	GA	79.10 ± 7.93	<0.00 5	118.17 ± 7.17	<0.00 5	74.37 ± 9.89	<0.00 5	88.97 ± 7.53	<0.00 5	11.53 ± 1.57	<0.00 5
	GA+ TEA	73.67 ± 7.24		104.73 ± 7.97		57.37 ± 8.97		79.87 ± 6.05		9.43 ± 1.41	
16 hours	GA	81.33± 10.80	0.01	111.17 ± 6.06	0.22	70.27 ± 5.44	<0.00 5	83.90 ± 3.74	<0.00 5	11.13 ± 1.55	0.03
	GA+ TEA	74.97 ± 7.31		109.53 ± 4.06		63.63 ± 5.40		79.07 ± 3.49		10.03 ± 2.14	
20 hours	GA	76.97 ± 6.33	0.02	108.80 ± 5.90	0.19	68.80 ± 6.67	<0.00 5	82.13 ± 4.83	<0.00 5	11.13 ± 1.14	0.01
	GA+ TEA	72.73 ± 8.13		110.70 ± 5.16		63.43 ± 4.03		79.20 ± 2.80		10.07 ± 1.70	
24 hours	GA	80.77 ± 9.60	<0.00 5	116.57 ± 6.83	<0.00 5	72.47 ± 7.28	<0.00 5	87.17 ± 5.63	<0.00 5	10.83 ± 1.23	0.17
	GA+ TEA	69.50 ± 6.88		107.23 ± 5.80		63.77 ± 2.76		78.17 ± 2.44		10.33 ± 1.58	

Discussion

Coronary artery bypass grafting (CABG) is one of the most common cardiosurgical interventions. In many institutions, CABG is performed without cardiopulmonary bypass (CPB), a modification which is commonly referred to as off-pump coronary artery bypass grafting (OPCAB). [15],[16]

The off-pump technique enables coronary revascularization on the beating heart, thereby reducing the risk of complications associated with CPB. However, OPCAB can be accompanied by hemodynamic alterations, postoperative pain, and respiratory dysfunction, requiring thorough monitoring and perioperative care. [17],[18]

Thus the anaesthesia management during CABG becomes of utmost importance. The principles of anaesthetic management are providing maximum cardiac protection by use of cardio-protective anaesthetic techniques, maintaining hemodynamic stability, enabling surgery exposure within limits of hemodynamic stability & providing excellent postoperative analgesia.

The addition of regional anaesthesia to general anaesthesia is an improvement in quality of recovery for patients undergoing CABG. Thoracic epidural analgesia

(TEA) was among the first anaesthetic techniques described for CABG. [19] TEA is physiologically justified for operations of coronary bypass on beating heart which fulfils the basic anaesthetic requirements i.e. maintenance of adequate coronary perfusion pressure and reduction of myocardial oxygen demand achieved by heart rate control and moderate decrease in myocardial wall tension.

Few studies have used Inj. Ropivacaine for GA+TEA in OPCAB surgery. [4]-[6] The concentrations used were different in all these studies. A dose-finding study [20] with 0.1%, 0.2% and 0.3% Ropivacaine demonstrated that 0.2% Ropivacaine provided the best balance between analgesia and motor block. To the best of our knowledge 0.2% concentration of Inj. Ropivacaine has been used only for postoperative period with or without opioid. [4], [6] Etches and colleagues [21] found that epidural 0.2% Ropivacaine at a rate of 10-14 ml/hr (but not 6 or 8 ml/hr) reduced PCA morphine requirements with little effect on pain scores after lower abdominal surgery & significant motor block in at least 30% of patients.

Hence the current prospective randomized study was designed to investigate the impact of plain 0.2% Ropivacaine in GA+TEA at 5-7ml/hr in OPCAB on perioperative hemodynamics, quality of pain control and intraoperative anaesthetic drug requirement.

We found no significant differences among the groups concerning demographic data including co-morbidities, preoperative EF and duration of surgery and of mechanical ventilation. Comparison of baseline hemodynamic parameters did not reveal any statistically significant difference between groups. The insertion of the thoracic epidural catheter was successful in all patients.

In the anesthetized patient, the major determinant of heart rate is the balance of the sympathetic and parasympathetic activity. High regional anaesthesia, including the upper five thoracic segments (T1-T5), blocks the cardiac afferent and efferent sympathetic fibers, resulting in loss of the chronotropic and inotropic drive to the myocardium. [3]

Using epidural anaesthesia with 0.2% Ropivacaine only, in combination with general anaesthesia, we observed significantly decreased heart rates throughout the surgical procedure [Table No. 2] and in postoperative period [Table No. 3] with maintenance of mean SBP, DBP and MAP.

The reduction in heart rate can be due to action through a decrease of β-receptor stimulation, but an increased vagal activity by TEA cannot be excluded. Similar results were found in other studies. [5], [6]

The pressures during LIMA harvest revealed no significant changes between groups. While the hemodynamic changes during distal anastomosis to anteriorly located coronary artery (LAD) can be related to moderate heart dislocation and compression, which is to maintain optimum surgical exposure and a relatively stable operational field. The most expressed hemodynamic changes are observed at a stage of shunting of coronary arteries located on back surface of heart-the right coronary and circumflex arteries. The basic mechanism is decrease in preload due to mechanical compression of the right heart chambers and as consequence reduced preload of left ventricle, leading to decreased cardiac output. The measures to prevent myocardial ischemia at this stage of operation include maintenance of relative bradycardia and normal MAP.

During the intraoperative period, changes in the mean SBP, DBP and MAP [Table no. 2] with GA+TEA were not significantly different than with GA alone. One possible explanation is that patients in the GA+TEA group remained capable of constriction of capacitance vessels in the remaining unblocked lower body segments, thereby increasing the mean arterial pressure intraoperatively. As 0.2% Ropivacaine alone does not show beneficial effect in hemodynamics intraoperatively as compared to GA, this implies that it is less effective in controlling the stress response of surgical procedure in our study. In the pre-extubation period, from hemostasis onwards [Table No. 2], SBP showed minimal fluctuations in GA+TEA group as compared to GA group. Possible explanation is adequate pain relief provided by TEA which prevented the rise in SBP in GA+TEA group.

In the postoperative period due to adequate pain relief and partly due to arterial and venous vasodilation, GA+TEA showed significant decreases in SBP, DBP and MAP [Table No. 3] after extubation.

The use of plain 0.2% Ropivacaine in this study as an epidural infusion in the postoperative period showed that the median VAS for pain in both groups was always

<40 mm. This suggests that pain was well controlled for most patients. But this monotherapy with Ropivacaine 0.2% seemed to be less effective as compared to other studies [4], [6] where VAS was maintained well below 20 mm at rest and 30 mm during cough with the use of Ropivacaine and opioid.

In the present study, the analgesic effect of epidural administration of 0.2% Ropivacaine reduced the requirements of intravenously administered Fentanyl (P = 0.001) and Pancuronium (P = 0.002) for general anaesthesia. The requirement of rescue analgesic in the study group was significantly low, with only 3 patients requiring Inj. Diclofenac 75 mg, once in each of the 3 patients.

Among patients receiving Ropivacaine at 5-7 ml/hr the median spread of sensory blockade at all times was from atleast T1 (upper limit of cephalad spread) to T8 (lower limit of caudal spread). The level of motor block was checked at frequent intervals with assessment of hand grip, wrist and elbow flexion; according to the ESSAM score. [14] Six patients complained of paraesthesia in dermatomes T1 and C8 in whom paraesthesia subsided on lowering the infusion rate. There were no major complications related to TEA.

In a study by Kirno et al, [9] the epidural catheter was sited >12 hr before surgery to decrease the risk of epidural hematoma in patients posted for CABG. There are some clinical disadvantages with the technique described in this study e.g., manpower issues (anaesthesiologists, nurse anaesthetists) for catheter insertion the day before surgery, increased preoperative monitoring and consequently increased costs. Olivier, [1] sited the thoracic epidural catheter in 60 patients immediately before induction with no neurological complications noted. Similar results were found by Kundu, [2] and Caputo [3] et al.

In OPCAB surgery, the need for heparinization is reduced to half the dose as that used for on pump CABG, making the use of epidural anaesthesia a more attractive approach. The factors like - presence of normal clinical history, normal coagulation studies and insertion of epidural catheter under strict protocols with appropriate neurologic monitoring, remarkably reduces the potential for permanent neurologic damage from an epidural hematoma.

The main limitation of the study was that it was not blinded. Although lack of masking can affect the assessment of clinical parameters, all patients were managed according to strict protocols, and data were collected in a consistent manner throughout.

There was no evidence of any adverse reaction or side effect in the form of anaphylaxis, skin rashes, bronchospasm or severe haemodynamic changes during the study.

Conclusion

This study demonstrated that thoracic epidural anaesthesia using plain 0.2% Ropivacaine along with general anaesthesia improves hemodynamic control, in terms of rate control, during operations of coronary revascularization on beating heart, significantly reduces the intraoperative anaesthetic drug requirement and provides good postoperative pain control.

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ORIGINAL ARTICLE

Study Of Socio-demographic Factors & Severity Of Pulmonary Tuberculosis.

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ABSTRACT

Background: Tremendous progress has been made in combating TB over the past ten years. But, dramatic changes in TB epidemiology are challenging TB control activities.

Aim: To study socio-demographic characteristics of PTB patients & to identify factors associated with severity of PTB.

Settings & design: An observational study at DOTS centersin E ward of Mumbai Municipal Corporation was carried out during 1st January 2004 to 30th June 2004.

Material & methods: Pre-tested structured interview schedules were fulfilled by interviewing new smear positive pulmonary tuberculosis patients registered during study period. Data regarding sputum smear examination report at the beginning & at the end of intensive phase were collected from respective DOTS centre. Data were entered in SPSS spreadsheet for analysis. chi squared test was used as a test of significance.

Results: 156 patients were interviewed with 67.3% males & 32.7% females. 24.2% were illiterate, 43.3% were unemployed, 52% belonged to socio-economic class IV & V, 53.8% were migrants. High positive sputum smear was associated with history of known TB contact in family (p= 0.03, OR= 1.773, 95%CI= 1.102- 3.094). Patients with high sputum smear positivity were more likely to show sputum smear non-conversion at the end of intensive phase (OR= 2.347, 95% CI= 0.953- 5.782), but the relationship just missed a statistical significance (p=0.053). **Conclusion:** Contacts in family play important role in causation of severe TB disease. Physicians or facilities treating TB patients should focus on education about TB & precautionary measures to decrease its transmission. Family members of TB patients need screening activities at regular interval.

Introduction

SIndia is the highest TB burden country and it accounts for more than 25% of the world's incident cases.[2]We have 1.9 million new TB cases annually with more incidence in north and in urban areas. There are about 3,25,000 deaths due to TB each year & it affects predominantly economically productive age group leading tohuge socio-economic impact. [3]India adopted the Directly Observed Treatment Short-course (DOTS) strategy for TB control since 1993.[5]

Migration, overcrowding & changes in lifestyles superadded with already existing adverse social factors caused dramatic changes in TB epidemiology in developing countries including India. [6]Emergence of of drug resistant (DR), multiple drug resistant (MDR)& extensive drug resistant (XDR) TB, total drug resistant (TDR) TB are the examples of such changes.

Present study was designed to re-assess socio-demographic characteristicsof new sputum positive (NSP) TB patients presenting for the treatment at DOTS centers & to find out factors are associated with severity of PTB.

Material and methods

Study was conducted at 24 DOTS centers located in E ward of Mumbai Municipal Corporation (MMC). All NSP TB patients initiated on category I treatment regimen of DOTS during 1st January 2004 to 30th June 2004 were interviewed as per pre-tested structured interview schedule. It included all socio-demographic variables along-with information regarding housing conditions, h/o TB contact, addictions, high risk sexual behaviors was also included in the schedule. Sputum examination results at the time of diagnosis & at the end of 2 months' intensive phase (IP) of anti-tuberculosis treatment (ATT) under DOTS were noted for all patients.

Ethical approval was obtained from Member secretary, Mumbai District TB control Society & ethical committee of Grant Medical College & J J Hospital. Verbal consent was taken from every patient before each

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interview. Data analysis was done using SPSS 11.0 software. Frequencies & percentages were established, Chi square test was used as test of significance wherever appropriate.

Definitions used:

1. Sputum smear positivity: Low positive sputum smear (LPS): Sputum smears graded as scanty & 1 as per DOTS criteria; High positive sputum smear (HPS): Sputum smears graded as 2 & 3 as per DOTS criteria. Patients with HPS were considered to have severe PTB, while patients with LPS were considered to have less severe PTB.

2. Nutritional status: After calculation of body mass index (BMI)6: Underweight:<18.50 Kg/m^2

Normal: 18.50- 24.99 Kg/m^2; Overweight:≥ 25.00

Results

Total 156NSP TB patients were studied. 67.3% (105/156) were males &32.7%(51/156) were females. Median age of the patients was 30 years (min= 14, max=71). Highest numbers of patients i.e. 31.2% were in the age group of 20 — 29 years followed by 25.5% in the age group of 30 — 39 years.[Figure- 1].

24.2%(38/156)patients were illiterate out of which 17 were males & 21 were females. 49.2%(77/156) patients had completed any of middle school standard. Only 3 patients were graduate& all were males.[Figure- 2]

43.3%(68/156) were unemployed. 58.8% (40/68) of unemployed patients, excluding students & housewives among unemployed, for patients, median duration of unemployment was 2 months (min=1 month, max= 180 months).TB was underlying cause of unemployment for 20.6% (14/68)of unemployed patients with median duration of unemployment as 3 months (Range= 11 months).56.7% (88/156) patients were employed with majority (45/88, 51.1%)of them were semiskilled workers, 26.1% (23/88) were unskilled workers. 3.4% (3/88) had monthly income between Rs. 500 to 749, 18.2%(16/88) had monthly income between Rs. 750 to 999, 44.3%(39/88) had monthly income between Rs. 1000 to 1999 &34.1%(30/88) had monthly income>Rs. 2000 as per prices at 2004. [Figure-3]

The highest number of patients i.e. 56/156 (37%) belonged to social class V&23/156 (15%) belonged to social class IV [Figure-4].Family support is vital in completion of ATT.(Non-adherence). But, 41.7% (65/156) were not living with own family major reason being migration (86.2% (56/65)).They lived in Mumbai as shown in [Figure-5]. 82 (52.8%) were married & out of 8 widowed patients, spouses of 3 had died due to TB.Total, 53.8% (84/156) were migrants.22.6%(19/84) of them were from various places in Maharashtra, 38.1%(32/84) were from UP, 9.5%(8/84) were from Bihar. Median duration of migration was 3 years. 34/84 (%) patients migrated in Mumbai since less than 2 years to seek job. 4/84 of migrants came to Mumbai for treatment of TB. One of them was from Nepal.

87.82% (137/156) patients resided in adverse housing conditions like slums, chawls, 7 were pavement dwellers, one patient resided at garage, one at temple & one at construction site. 92.70% (127/137) had overcrowding in house, 96.35% (132/137) did not have adequate cross ventilation which dramatically dilutes the concentration of infectious droplet nuclei.[16]

17.9%(28/156)patients had no any kitchen & were taking their meals outside, all of them were migrants. 2/128 (1.3%) patients cooked food on footpath, both of them were migrants. 99/128 (77.34%) patients were having no separate kitchen, it was with living room.65/128 (50.8%) used fuel in kitchen that produced smoke which can alter the course of TB infection.

30/156 patients had other co-morbidities like diabetes mellitus (DM), is chaemic heart disease(IHD), arthritis requiring long term treatments. Median duration of detection of co-morbidity was 15 months (minl, max=240 months). 3/30 (10%) patients were known patients of HIV/AIDS, 2 of them received ART concurrently with ATT, 1 had discontinued it. 13/ 157 patients had DM,

Tobacco chewing was elicited from 42.3%(66/ 156) since median duration of 9 years (min=1 year, max=48 years). Out of 52 smokers, 38.46% (20/52)smoked cigarettes &6 1.54%(32/52) smoked bidi. 19/52 were regular smokers since median of 10 years (min=2, max=30 years). They smoked for median of 5 bidi or cigarettes per day (min=2, max=15).37.8%(59/ 156) patients were alcoholics. Majority of them consumed country liquor. 28.81% (17/59) were regular alcoholics since median of 13 years (min=5, max=40years).

4/156 (2.56%) males gave h/o visiting female sex workers (FSWs) for 2 to 4 times in their lifetime. 3/

156patients gave h/opremarital sexual relation. Out of 51 females, 4 were known FSWs since median duration of 12.5 years (min=2, max=20 years).

52.6%(82/156) had h/o contact with known TB patient prior to diagnosis. Majority of contacts were from family [Figure-6]. Median duration since contact was 12 months (min=1, max=240 months). Known TB contacts of 85.4%(70/82) patients had received ATT from government or municipal dispensary, 2.5%(4/82) from pvt, of 2.5%(4/82) did not take any ATT & treatment h/o 2.5%(4/82) was not known to the patient .

Overweight offers some protection against TB. We had only 2% (3/156) patients as overweight. 63%(99/156) patients were underweight [Fig-3] in our study. Median weight of patients was 42 kilograms (min=25kg, max=9Okg). Mean height was 156.17 centimeters (±SD: 8.32). Mean body mass index (BMI) was 17.75 kg/meter2 (±SD: 3). (Figure- 7)

At the initiation of ATT, 49% (76/156) patients had HPS & 51% (80/156) had LPS. 25% (38/156)patientshad grade 3 of sputum smear positivity for AFB (Figure- 8). 30/38were in the 15- 49 year age group. 30.77% (48 /156) had known TB contact in family, 54.2%(26/48) of them had HPS at the initiation of IP as compared to 30.6% (11/36) who had known TB contact at other than family. HPS was associated with h/o known TB contact in family (p= 0.03, OR= 1.773, 95%CI= 1.102- 3.094) as compared to contact at other places (Table- 2). HPS was not associated with any other socio-demographic factor like age, overcrowding & cross ventilation in house, smoking, tobacco & alcohol consumption, high risk sexual behavior, nutritional status, etc (p> 0.05).

Out of 156 patients, 125 (80.12%) had sputum smear examination at end of IP. 60/125 had HPS at the initiation of ATT & 65/125 had initial LPS. 15.2% (19/125) did not show sputum conversion. 21.7% (13/60) of patients with HPS at the initiation of ATT did not convert while only 9.2% (6/65) of patients with LPS at the initiation of ATT did not convert sputum smear at the end of IP. We tested association of sputum smear positivity at initiation of ATT & sputum smear conversion at the end of IP, which just missed the statistical significance (p= 0.053),but patients with initial HPS were more likely to show sputum smear non-conversion at the end of IP (OR= 2.347, 95% CI= 0.953- 5.782)

Discussion

ETB affects predominantly economically productive age group. [3]56.7% patients in our study were in the age group of 20-39 years. We observed low proportion of females in all age groups.

We had 23/156 patients as adolescents, out of them 10 did not have scar of BCG which is mainly beneficial to prevent serious disseminated disease in children. [7]47.4% (74/156) patients were having scar of BCG on left deltoid.

41.7% patients in our study were lacking family support. We noted median duration of migration till developing TB disease as 3 years. Migrants need more support from treatment providers & present program needs more provisions for them like regular screening[10], referral & tracking activities once on ATT.TB is one of the many threats to sex workers due to all adverse conditions they face.[16]We had, 4/156 (2.56%) were FSWs. 3 out of 4 FSWs were not available for sputum examination after IP. They should be given health education regarding TB & HIV and counselled accordingly for treatment adherence &necessary by trained personnel. Thus, we observed that there are no major changes in socio-demographic characteristics of NSP-TB patients.

We observed h/o TB contact in family was associated with HPS which denotes severity of TB. Household exposure to TB is considered as most intense exposure to TB.[19] Out of 82 patients who gave history of known TB contact, 39 patients had TB contact in family. All were living in overcrowded & poor housing conditions which facilitate spread of TB infection that is too with high infective dose of TB bacilli in absence of cross-ventilation. Family size also influence chance of exposure to TB infection from the patient.[16] Median number of persons exposed to patient at residence was 4 (min=1,max=18). Chief complaints of cough with expectoration were noted in at least one person living with them in 4/156 (2.56%) patients. It also suggests that there is a need to educate PTB patients to take all necessary precautionary measures to decrease TB transmission to community & family.

Findings from the present study reiterate the fact that there are no major changes in socio-demographic characteristics of NSP-TB patients &that contacts in family play important role in severity of TB disease than

contacts at other places. Physicians or facilities treating TB patients should focus on educating patient regarding precautionary measures to decrease TB transmission to others. We evaluated various factors associated with initial HPS & sputumconversion rate following two months of ATT under DOTS in E ward of MMC. TB contact in family was associated with HPS & patients with HPS were more likely not to convert sputum smear at the end of 2 months of IP. Further studies are needed to confirm findings. Association of factors could be better understood through a longitudinal study with a larger sample.

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ORIGINAL ARTICLE

Efficacy and safety of short course of Dexamethasone and Vitamin C in patients of simple dengue fever-An observational study

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ABSTRACT

Dengue is the most common arbo-viral disease worldwide. Patients with dengue can experience a variety of serious complications including thrombocytopenia, bleeding and shock. These problems occur as plasma viraemia is resolving and are thought to be immunologically mediated. Early corticosteroid therapy may prevent the development of such complications. Glucocorticoids are used in this condition; without any objective evidence of benefit. Vitamin C is recommended in many viral diseases, also empirically. Hence this study was conducted to assess the efficacy of steroids and vitamin C in simple dengue fever. We included patients (age:18-60y) of dengue fever in this study and divided them into three treatment groups viz. Dexamethasone 8mg/d, CELIN 500mg / 8h and BIO-C 1 tablet /8h.Diagnosis was confirmed by Dengue NS-1 test. They were assessed clinically and biochemically, on day 1,3,8,15 and 22.Laboratory parameters included hemogram, BSL, platelet count, SALT and serum creatinine. Results were analyzed by Students unpaired 't'test.Between August 2010 and September 2012, we enrolled 250 patients attending OPD of Dhanashree Hospital, New Sangavi, Pune 411027.They were given one of the three treatments in addition to routine care. Baseline characteristics were similar across the groups. Only 140 patients attended all five visits and their data were subjected to statistical analysis. All patients recovered fully and adverse events were infrequent. There was a trend toward hyperglycemia in the steroid (n=40) recipients. Vitamin C treatment was associated with better clinical response and lesser decline in platelet count as compared to dexamethasone therapy. Patients in BIO-C (n=55) group recovered faster. Use of vitamin C was associated with rapid clinical & biochemical recovery, while steroid treatment was not beneficial in patients of simple dengue fever.

Keywords: Dengue fever, Dexamethasone, Vitamin C, BIO-C.

Introduction

Dengue is a self-limited, systemic viral infection transmitted between humans by mosquitoes, mainly by *Aedesaegypti*mosquito and also by *Aedesalbopictus*. It is caused by one of four single stranded positive sense RNA viruses (dengue virus type 1 through dengue virus type 4), also referred to as serotypes of the genus flavivirus (family Flaviviridae). It causes a wide spectrum of illness from mild asymptomatic illness to severe fatal dengue hemorrhagic fever/dengue shock syndrome (DHF/DSS).

The epidemiology of dengue fevers in the Indian subcontinent has been very complex and has substantially changed over almost past six decades in terms of prevalent strains, affected geographical locations and severity of disease. The rapidly expanding global footprint of dengue is a public health challenge with an economic burden that is currently unmet by licensed vaccines, specific therapeutic agents, or efficient vector-control strategies. The global burden of dengue is large; an estimated 50 million infections per year occur across approximately 100 countries, with potential for further spread[1].

The management of dengue virus infection is essentially supportive and symptomatic. No specific treatment is available. However, there are Indian studies which have contributed in terms of better management of DHF/DSS. A rapid response to platelet and fresh frozen plasma(FFP) transfusion is reported in a study[2]. Anti-D has been used in children with DHF and severe refractory thrombocytopenia[3].But there have been no clinical studies done on treatment using Vitamin C preparations in uncomplicated dengue fever.

There is no evidence that the virus infects endothelial cells, and only minor non specific changes have been detected in histopathological studies of the

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microvasculature [4,5]. Preliminary data suggest that transient disruption in the function of the endothelial glycocalyx layer occurs[6,7]. This layer functions as a molecular sieve, selectively restricting molecules within plasma according to their size, charge and shape. Hypoalbuminemia and proteinuria are observed during dengue infection; proteins upto and including the size of albumin are preferentially lost; this is consistent with a small but crucial change in the filtration characteristics of the glycocalyx[8]. Both the virus itself and dengue NS1 are known to adhere to heparin sulfate, a key structural element of the glycocalyx[9]. Steroids have immunosuppressive action[10] and might prevent this disruption.

Vitamin C has been recommended in many viral diseases although its role has not been assessed in controlled clinical trials. Hence we thought of this study to assess its role.

Patients And Methods

The study was conducted from August 2010 till September 2012.This study was done in the OPD, Dhanashree Hospital, New Sangavi, Pune. Patients aged 18-60 years and clinically suspected of dengue were included in the study. Patients complaining of fever less than 72 hrs duration were included. Written informed consent and relevant history was taken and given treatment immediately. Exclusion criteria were:

i. Symptoms suggesting other infection,

ii. Dengue-related complications,

iii. Chronic disease-DM, HT,

iv. Organ dysfunction- liver, kidney

v. Women with positive UPT

Commercially available NS-1 kits were obtained from J.Mitra and were used for diagnosis.

Methods : Patients were divided into 4 treatment groups. Each receiving

1. Conventional treatment-oral/iv fluids and antipyretics were considered as CONTROL
2. Injection Dexamethasone(DEXA): 8 mg/day i.m
3. Tablet CELIN: 500 mg/day p.o
4. Tablet BIO-C:1000 mg/day p.o

Standard Case report form was filled on the basis of history and clinical assessment (which was scored from 0 to 15) of the patients. Laboratory parameters were measured on day 1,3,5,8,15& 22.Hemogram, Blood sugar level, Serum alkaline phosphatase, Serum creatinine, Urine routine and microscopy, Platelet count, BT/CT, and USG-abdomen were recorded. Any adverse events like epigastric pain, vomiting, etc were noted. Parameters used wereClinical Relief, Platelet Count > 1,00,000/mm^3, SALT : WNL and NS-1:negative. Statistical analysis was done using Student's unpaired '*t*'test.

Results

Total 250 patients were screened, the distribution of which is given below:

Patients tested NS-1 negative: 41

Patients who did not attend all visits: 54

Patients who developed complications: 15

Total Patients assessed were: 140.

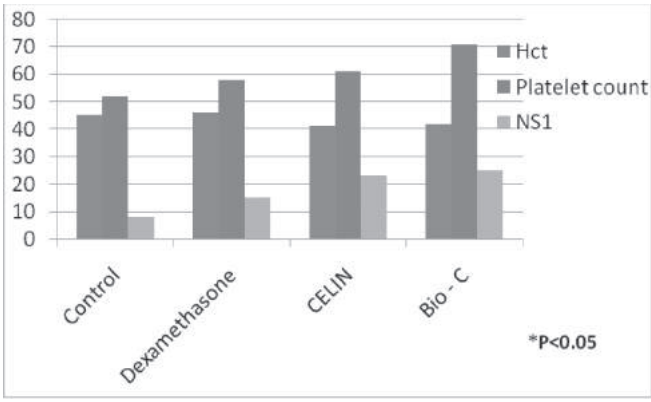
There was no significant difference in the baseline features between the groups (Table 1). Baseline level of haemoglobin, total blood counts, serum alkaline phosphatase, serum creatinine & platelet counts were also comparable in all the groups.

TABLE 1 : BASELINE CHARACTERISTICS

	C (n=20)	Dexa (n=40)	Celin (n=45)	Bio-C (n=35)
Age (y)	35+11	36+14	34+12	38+13
Sex (M/F)	14/6	26/14	30/15	24/11
Hb (g/dL)	12.5+1.4	13.6+1.6	12.8+1.5	13.1+1.7
WBC (/uL)	3200+140	3750+170	3500+160	3400+150
BSL (mg/dl)	103+18	115+16	110+12	108+17
SALT (IU/l)	32+5	25+8	30+6	28+7
Creat (mg/dl)	0.8+0.1	1.1+0.1	1.2+0.1	0.9+0.1
Platelet (10/L)	144+31	140+32	135+35	142+34
P/S Infection	12/8	29/11	36/9	27/7

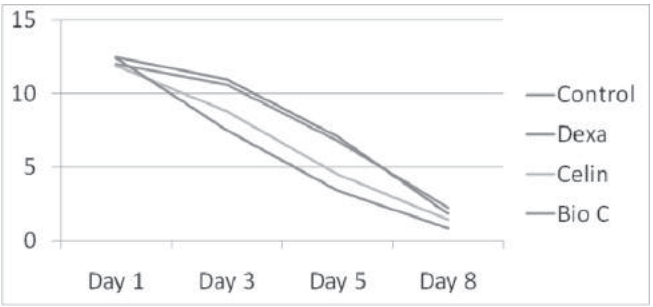
P>0.05

Figure 1 : EFFECT OF VARIOUS TREATMENTS ON LAB PARAMETERS



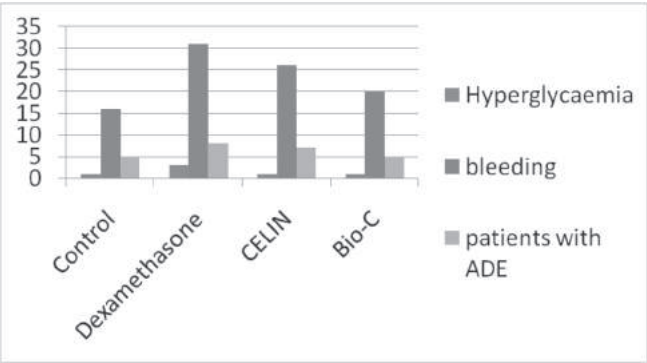
The patients in Control (C) and Dexamethasone (Dexa) treated group show increase in hematocrit values and decline in platelet counts and reduction in negative NS1 values.The patients in Celin and Bio-C treated group showed fall in hematocrit values and showed less decline in platelet counts and increase in negative NS1 values.

Figure 2: EFFECT OF VARIOUS TREATMENTS ON CLINICAL RECOVERY



The line graph for Control and Dexamethasone groups show gradual recovery whereas those for Celin and Bio-C show rapid recovery from day 3 onwards. However, all patients improved by day 8.

Figure 3: ADVERSE EVENTS IN DIFFERENT GROUPS



The adverse events noted were mainly hyperglycaemia, episodes of bleeding and other drug related adverse effects. The incidence of hyperglycaemia and episodes of bleeding werenoted mainly in the group treated with Dexamethasone. Similarly ADR related to drug were more common in this group.

Discussion

In this small study, we observed that early institution of low dose steroid treatment was not associated with better clinical recovery or recovery of biochemical parameters like haematocrit and platelet count. However the incidence of hyperglycaemia and drug related adverse effects was found to be more in this group. The transient disruption of the function of glycocalyx is reported to occur early in the phase of the disease. Hence we thought of using steroids early in the course of the disease. However it is possible that some of our patients might have consulted for the first time after 5 days of fever. This might have affected the results. Secondly the dose of steroid was kept the same irrespective of body weight. Hence the effect of steroids may need further studies by changing the dose and using them strictly during the first 5 days of dengue infection.

Vitamin C has been recommended empirically and we have found it to be beneficial in hastening the clinical and biochemical recovery. The exact mechanism by which vitamin C acts is not known. Dengue fever complications are mainly because of increased oxidative stress and the cascade of reactions occurring along with it. Vitamin C is reported to have anti-oxidant properties which might be playing a role in preventing these reactions. Bio-C contains phytonutrients in addition to vitamin C and the better results obtained in this group might be because of these additional constituents.

Conclusion

The study clearly demonstrates that short dose of steroids has no clinical or biochemical benefit in the treatment of simple dengue fever.

Use of Vitamin C preparations was assosciated with better clinical and biochemical recovery.Early institution of vitamin C in the treatment of dengue fever might be considered as safe, efficient and tolerable treatment. However this is a small study and needs confirmation by large multicentric clinical trials.

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ORIGINAL ARTICLE

Evaluation of efficacy, safety and tolerability of Ayurvedic drug Cap. SC_3 and CCRAS formulation - AYUSH-RP in Sickle Cell Disease- A Pilot Study

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ABSTRACT

Sickle Cell Anaemia is hereditary/genetic disease confined to red blood cell. The basic defect is in the structure of haemoglobin molecule. The disease is characterized by its sickling phenomenon. The patient suffers from various symptoms and complication of crisis. The disease is common in the state of Maharashtra and highest prevalence amongst tribal population residing in the areas of Satpuda hilly ranges from the Nandurbar district. We selected 90 patients from this area and divided them in to three equal groups. First group received folic acid, Second group received polyherbal drug SC_3 and third group received Ayurvedic coded drug provided by CCRAS (AYUSH RP). All the patients were examined for 29 parameters which includes clinical examination and haematological and biochemical investigations. This is a randomized open labeled pilot study for a period of 6 months.

Conclusion: We found the drug beneficial for improving quality of life, reduction in the severity of crisis, pain and the drug is found to be safe.

Key Words: Sickle Cell Disease, SC_3, AYUSH RP, Bilwa, Ayurvedic Drug,

Introduction

Sickle cell anaemia (SCA) is a genetic disorder confined to the red blood cells. The basic defect is in the structure of haemoglobin molecule inside the cell. Due to this defect the red blood cells acquire sickle like shape in deoxygenative condition. Because of this peculiar sickling phenomenon the haemoglobin is recognized as Sickle cell Haemoglobin (HbS). This is genetic mutant form of normal Haemoglobin (HbA). It is a single gene defect i.e. 6^{th} amino acid (Glutamic acid) in β chain of HbA is replaced by Valine in HbS. Due to this defect there is early destruction of red blood cells leading to condition of anaemia known as sickle cell anaemia (SCA).

The common symptoms of the disease are mild to severe anaemia, mild jaundice, and severe joint pains. In addition one of the typical symptom experienced by majority of the patients is known as "Crisis". If prompt and proper medical intervention is not made available, patient is likely to succumb to death.

Due to repeated episodes of crisis there is multiple organ damage like cerebro-vascular accident in brain, respiratory failure in lungs, renal failure in kidneys and avascular necrosis of long bones. Avascular necrosis of femoral head is common. Usually the size of spleen is enlarged (Splenomegaly) and in few cases hepatomegaly is observed.

The long term studies have emerge the following observations:

- It injures every organ of the body, but does not affect every one in the same way.
- Differ in both extent of complication and severity from individual to individual.

Ultimately the disease is complicated and painful.

Sickle cell disorder is a genetic disorder and transmitted from one generation to other in autosomal recessive pattern. It is found in two forms one heterozygote and other homozygote. Heterozygote individual usually do not suffer from any complications of the disease however is likely to transmit this gene to the next generation and hence known carrier. Homozygote

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individual always suffer from various symptoms of the disease and is known as sufferer.

Our institution has carried out extensive screening for sickle cell disorder in different tribal areas of Maharashtra and found high prevalence amongst Bhill and Pawara Tribal population groups residing in the Satpuda hilly ranges of the Nandurbar district carrier prevalence is (1 in 5). We established community control program center in this high prevalence area for our all activities.

Aim

Evaluation of Efficacy, safety and tolerability of Ayurvedic drug Cap. SC_3 and CCRAS Formulation (AYUSH-RP) in Sickle Cell Anaemia

Objectives

1) To assess effect on different clinical parameters such as pallor, pain, crisis.

2) To assess effect on different haematological parameters.

3) To assess effect on different biochemical parameters.

Material and Methods

Prior to start clinical trial the project was submitted to our institutional ethical committee and institutional review board and permission was obtained.

During the screening carried out at our sickle cell clinic newly diagnosed patients were enrolled for the study. The patient and parents were informed about this trial and consent and assent of adolescent patients was obtained. The diagnosis was carried out by testing the blood samples by performing solubility test and cellulose acetate membrane electrophoresis at alkaline pH 8.6. Additional confirmation was carried out by performing similar test on parents blood sample. Out of these 90 patients were selected for trial by considering inclusion and exclusion criteria. Detail demographic data of a patient and family was recorded in prescribed proforma.

In this randomized open label pilot study, 90 patients were randomized using 30 permuted blocks of block size 3 were selected by using computer generated random numbers and were divided in three groups. Each patient was subjected to systemic investigation, haematological and biochemical investigations for baseline data.

Study Groups

The study was organized in three treatment groups. Each group consists of 30 patients. The groups were known as Group A, B & C. Group A was control group and given 5 mg of folic acid daily. B Group known as trial group received a polyherbal preparation known as SC_3 in a dose of 500 mg twice daily. SC_3 contains Aegle marmelos (L.) Correa ex Roxb (Bilva), Tephrosia perpurea (Linn.) Pers (Sharpunkha), Aloe vera (Willd.) Hook.F. & Thoms (Kumari), Eclipta alba (L.) Haask (Bhringraj), Tinospora cordifolia (Willd.) Hook.F. & Thoms (Guduchi) and Phyllanthus amarus SCHUM. & THENN. (Bhumyamalaki). Group C as a trial group received Ayurvedic coded herbo-mineral drug AYUSH –RP in a dose of 1000 mg twice daily provided by CCRAS, New Delhi. Follow up of each patient was taken at two months interval till 6 months. Each patient received treatment for period of 6 months duration on OPD basis. Confidentiality of all three groups was maintained.

The ingredients of trial drugs (group B & C) as per ayurvedic methodology are known to have following properties: 1) Improves Rakta-Dhatvagni- A Factor essential for formation of good quality of Rakta Dhatu (blood components) 2) Action on liver and spleen:- Liver and spleen are most important organs for formation and destruction of blood components. 3) Tridoshashamaka:- In the Samprapti (Pathogenesis) of Sickle cell Disease all the three Doshas are vitiated. Vata Dosha is responsible for premature destruction and abnormal shape, Pitta gets vitiated due to excess destruction of RBC, Vatavriddhi and Prakrut Kaphakshaya are observed resulting in to abnormality in shape of RBC and low immunity (Prakrut Kapha is termed as Bala). Due to abnormal shape of RBC normal life expectancy of cell is reduced and causes early destruction, leading to Pittavriddhi as Pitta resides in association with Raktadhatu. Clinically this disease is Apatarpanajanya (depletion) and has main symptoms like Panduta (Pallor), Kamala (Jaundice) and Sandhishoola (Joint Pain). 4) Rasayan- improves immunity and having anti-oxidant property.

The study was conducted in MAM's Sickle Cell Dawakhana at Roshmal BK, Tal Dhadgaon, Dist.

Nandurbar, Maharashtra (21.50 N – 75 0 E), S.S.A.M.'s Ayurved Rugnalaya-Sane Guruji Arogya Kendra Hadapsar, Pune-28, National Institute of Immunohaematology (ICMR) Mumbai and Central Pathology Laboratory Dhule. Study was conducted as per Good Clinical Practices (GCP) guidelines.

Inclusion Criteria

1. Newly diagnosed SCA patients

2. Age >= 15 to 30 years

3. Sex: Both male and female

4. Solubility test on blood- positive

5. Hb electrophoresis at alkaline pH (8.6) on blood documented Sickle Cell Disease HbSS

Exclusion Criteria

1. SCA associated with other diseases like DM, HT, Thalassemia, Chronic cardiac dysfunction

2. Pregnant women, old patients who are already under treatment

3. Hepatic, renal dysfunction, patients unable to provide written informed consent

4. History of pain rises > 12 in last 6 months;

5. History of pain crises treated by any other medical faculty in last 4 days

6. Use of any drug other than investigational drug in last one month

7. Significant respiratory compromise function (initial $SPO_2 < 90\%$) and/or acute chest pain.

8. Neurological symptoms

9. Concurrent suspected/documented bacterial infection and use of antibiotics for temperature.

10. History of chronic blood transfusion.

11. Sr. Creatinine. > 2 mg/dl; Bilirubin Total > 10 mg/dl

12. Otherwise not found suitable by the principal investigators after physical examination

Withdrawal Criteria

1. If a patient develops any adverse effects,

2. Not responding to treatment and aggravation of pain Crises and other symptoms.

3. If patient requires blood transfusion

4. Patient refuse to continue treatment

5. At patients discretion

6. Irregular in treatment / follow up

7. Non compliant with treatment.

Parameters for Efficacy Assessment

Initially (Base Line)

1. Physical examination – Body Weight in Kgs | Height in cms

2. Clinical examination of all systems

3. Assessment of Crises (numbers in last 6 months / severity of episodes / history of hospitalization

4. Hematological investigations– CBC with RBC indices, ESR | Platelet count | Reticulocyte count | Hb electrophoresis and Hb fractionation studies by HPLC method.

5. Biochemical investigations– Sr. Ferritin | LFT I RFT.

6. Urine Routine Exam. – For sugar, albumin or other abnormalities.

Follow Up Studies at interval of 2 months till 6 months:

Clinical Assessment, Routine Haemogram along with Reticulocyte count and LFT

Follow up Studies at the interval of 6 months:

Similar as baseline including all clinical, haematological, biochemical and urine investigations

Details of instrument:-

Blood Investigations were conducted at Institute of Immunohaematology (ICMR) Mumbai ICMR for Haemoglobin fractionation by Bio-Rad High Performance Liquid Chromatography (HPLC).

Haematological Parameters were investigated on Haemogram-18 Parameters by Micros 60, Blood cell counter, ABX Diagnostics, France at Central Pathological laboratory Dhule.

Collection of sample and transport: -

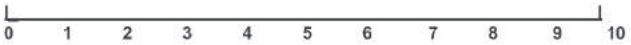
Subjects were given full idea about the blood investigations and consent was obtained. Intravenous Blood Samples were collected in EDTA bulb and plain bulb at the project site and were transferred to the laboratory in a vaccine carrier container maintaining the cold chain.

Parameter for Pain assessment: -

The Oxford Pain Validity Scale (OPVS) was designed specifically to examine issues regarding validity in pain trials and is described in detail as follows

No pain = 0; Mild Pain 0 to 3; Moderate pain 4 to 6; Severe pain 7 to 10

Oxford pain Scale



End points and Monitoring:-

The subjects were undergone clinical and pathological blood investigation of various 28 parameters. Clinical parameters- weight, pallor, sclera, abdominal examination, spleen examination, pain and pathological parameters- CBC with RBC indices, ESR, Reticulocyte count, Hb fractionation (HPLC), LFT, RFT. The subjects were closely monitored bi-monthly for the period of 6 months from the date of enrollment and when and as required. During this period they were not supposed to take any other supplementary medication.

Statistical Analysis:

Data of all the randomized treatment groups was tabulated in excel format in intension for statistical analysis. Methodology of the study endpoint was established and the data was compared within the group and among the three groups. The data was analyzed manually and supervised by an eminent statistician and officer of Central Council for Research in Ayurveda and Siddha. New Delhi. Clinical and pathological 28 variables of the enrolled participants were subjected to statistical analysis.

Role of Funding Source:

The study was funded under the extra mural research Scheme of Central council for Research in Ayurveda and Siddha, Department of AYUSH, Ministry of Health and Family Welfare New Delhi.

Acknowledgment:-

We are thankful for continuous support and guidance from Dr.Graham Serjeant, Dr.S.L.Kate, Dr. Kanjaksha Ghosh, Dr.Roshan Colah and Dr.B.C Mehta. We are also thankful to the patients and their parents who supported us in this study.

Results:-

Comparative chart of Group A, B, C with mean +/- Standard Deviation

Variables	Group A Mean +/- S.D.		Group B Mean +/- S.D.		Group C Mean +/- S.D.	
Weight	38.23	3.6	41.73	2.3	39.87	2.5
Pallor	0.47	0.7	0.27	0.5	0.23	0.5
Sclera	0.93	0.7	0.73	0.8	0.60	0.6
Spleen	1.06	0.9	1.13	1.4	0.88	1.0
Hb	9.97	1.0	10.46	1.0	9.95	1.3
HbA2	3.22	0.7	3.32	0.7	3.19	0.7
HbF	16.96	15.1	15.42	2.3	17.44	3.5
HbS	75.85	15.3	78.09	3.1	76.42	3.4
RBC	4.32	0.5	4.61	0.6	4.32	0.7
HCT	30.36	3.6	32.26	4.2	30.15	4.1
MCV	71.03	4.2	70.61	3.2	70.39	3.7
MCH	23.41	1.9	22.97	2.1	23.07	2.6
MCHC	32.93	2.7	32.52	2.8	32.80	3.0
Retic	2.13	1.3	2.23	1.1	1.97	1.2
Plt.ct	3.26	1.1	2.84	0.8	3.08	1.2
ESR	8.47	17.3	11.50	27.4	14.43	20.0
Ferritin	285.43	219.3	317.79	212.6	253.39	206.8
Prot. Total	6.80	1.0	6.78	0.9	6.90	0.7
Albumin	3.83	0.7	3.94	0.6	3.91	0.6
Globulin	2.96	0.8	2.87	0.8	2.99	0.8
Total . Bil.	2.20	1.4	2.23	1.6	1.83	1.6
D.Bil.	0.61	0.6	0.61	0.8	0.50	0.8
Indirect .Bil	1.58	1.0	1.62	1.1	1.33	1.2
SGOT	36.77	24.6	39.30	26.2	34.17	17.8
SGPT	54.43	74.1	69.17	59.2	60.43	67.7
Alk.Phosp	97.73	61.1	106.33	57.5	87.23	90.7
BUL	19.10	7.1	17.37	15.6	17.83	5.3
Creatinine	0.84	0.2	0.78	0.2	0.79	0.1

In the above table the mean +/- SD all the variables is compared within all three groups and it is observed that the subjects enrolled in the study have similar mean variables (+/-S.D.) {At 5% significance level} indicating that the data is homogenous.

Comparative chart of Group B and C

Laboratory and Clinical parameter outcome	Mean Difference Group B	Mean Difference Group C	P-Value	Level of Significance
Weight	0.017	0.2	0.7577	Non Significant
Pallor	0.133	0.1	0.7948	Non Significant
Sclera	0.367	0.267	0.5713	Non Significant
Spleen	-0.07	-0.1	0.9250	Non Significant
Hb	-0.253	0.08	0.2567	Non Significant
HbA2	-0.12	-0.093	0.8769	Non Significant
HbF	0.483	-0.073	0.4701	Non Significant
HbS	0.223	0.343	0.8877	Non Significant
RBC	-02	0.052	0.1373	Non Significant
HCT	-0.813	0.39	0.2701	Non Significant
MCV	1.423	0.413	0.2535	Non Significant
MCH	0.053	0.13	0.9004	Non Significant
MCHC	-1.29	-0.99	0.6863	Non Significant
Retic .Ct	0.223	0.133	0.7551	Non Significant
Plt. ct	0.096	-0.058	0.5801	Non Significant
ESR	6.333	-1.333	0.2206	Non Significant
Ferritin	-72.071	-42.83	0.5913	Non Significant
Prot. Total	0.127	-0.067	0.3715	Non Significant
Albumin	0.157	0.023	0.3885	Non Significant
Globulin	-0.063	-0.09	0.8980	Non Significant
Total . Bil.	0.47	0.173	0.4806	Non Significant
D.Bil.	0.257	0.093	0.4228	Non Significant
Indirect .Bil.	0.213	0.08	0.6455	Non Significant
SGOT	-3.173	0.567	0.5205	Non Significant
SGPT	-17.473	-2.9	0.3786	Non Significant
Alk.Phosp	-8.733	21.5	0.1285	Non Significant
BUL	3.793	0.267	0.2467	Non Significant
Creatinine	-0.013	-0.023	0.8397	Non Significant

It is observed that the P value of Comparative B and C group exhibit non significant (>0.05) criterion in various parameters. This means that Group B and Group C have same pharmacological action on the patients.

Comparative chart of Group A and C

Laboratory and Clinical parameter outcome	Mean Difference Group A	Mean Difference Group C	P-Value	Level of Significance
Weight	1.35	0.2	0.1536	Non Significant
Pallor	0.167	0.1	0.6684	Non Significant
Sclera	-0.033	0.267	0.0810	Non Significant
Spleen	0.277	-0.1	0.1306	Non Significant
Hb	0.007	0.08	0.8106	Non Significant
HbA2	-0.273	-0.093	0.2987	Non Significant
HbF	3.12	-0.073	0.2638	Non Significant
HbS	-1.4	0.343	0.5439	Non Significant
RBC	0.048	0.052	0.9757	Non Significant
HCT	-0.103	0.39	0.6236	Non Significant
MCV	0.527	0.413	0.9121	Non Significant
MCH	0.163	0.13	0.9547	Non Significant
MCHC	-0.883	-0.99	0.8839	Non Significant
Retic .Ct	0.15	0.133	0.9582	Non Significant
Plt. ct	0.05	-0.058	0.7097	Non Significant
ESR	3.2	-1.333	0.3511	Non Significant
Ferritin	-109.216	-42.83	0.2326	Non Significant
Prot. Total	0.083	-0.067	0.5029	Non Significant
Albumin	0.25	0.023	0.1711	Non Significant
Globulin	-0.133	-0.09	0.8244	Non Significant
Total . Bil.	-0.037	0.173	0.5993	Non Significant
D.Bil.	-0.05	0.093	0.4181	Non Significant
Indirect .Bil.	0.013	0.08	0.8134	Non Significant
SGOT	-5.4	0.567	0.2853	Non Significant
SGPT	-2.9	-2.9	1.0000	Non Significant
Alk.Phosp	5.4	21.5	0.4232	Non Significant
BUL	2.467	0.267	0.1810	Non Significant
Creatinine	-0.01	-0.023	0.7928	Non Significant

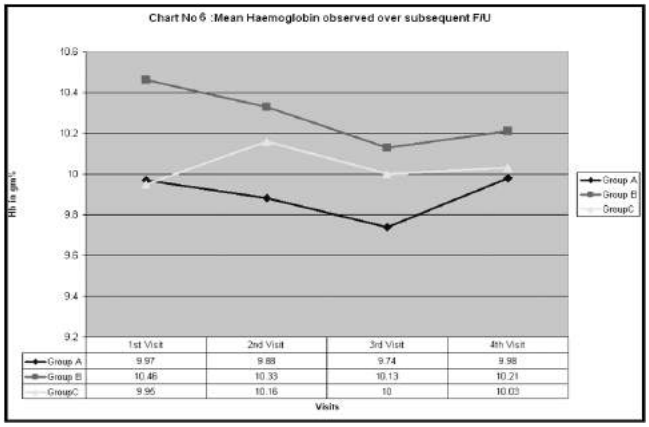
It is observed that the P value of Comparative A and C group exhibit non significant (>0.05) criterion in various parameters. This means that Group A and Group C have same pharmacological action on the patients.

Comparative chart of Group A and B

Laboratory and Clinical parameter outcome	Mean Difference Group A	Mean Difference Group B	P-Value	Level of Significance
Weight	1.350	0.017	0.0878	Non Significant
Pallor	0.167	0.133	0.8333	Non Significant
Sclera	-0.033	0.367	0.0412	Non Significant
Spleen	0.277	-0.070	0.2560	Non Significant
Hb	0.007	-0.253	0.3224	Non Significant
HbA2	-0.273	-0.120	0.3712	Non Significant
HbF	3.120	0.483	0.3482	Non Significant
HbS	-1.400	0.223	0.5705	Non Significant
RBC	0.048	-0.200	0.1060	Non Significant
HCT	-0.103	-0.813	0.4869	Non Significant
MCV	0.527	1.423	0.3527	Non Significant
MCH	0.163	0.053	0.8354	Non Significant
MCHC	-0.883	-1.290	0.5630	Non Significant
Retic .Ct	0.150	0.223	0.8124	Non Significant
Plt. ct	0.050	0.096	0.8543	Non Significant
ESR	3.200	6.333	0.5985	Non Significant
Ferritin	-109.216	-72.071	0.5079	Non Significant
Prot. Total	0.083	0.127	0.8583	Non Significant
Albumin	0.250	0.157	0.5804	Non Significant
Globulin	-0.133	-0.063	0.7359	Non Significant
Total . Bil.	-0.037	0.470	0.2051	Non Significant
D.Bil.	-0.050	0.257	0.0987	Non Significant
Indirect .Bil.	0.013	0.213	0.4588	Non Significant
SGOT	-5.400	-3.173	0.7355	Non Significant
SGPT	-2.900	-17.473	0.4034	Non Significant
Alk. Phosp	5.400	-8.733	0.3600	Non Significant
BUL	2.467	3.793	0.6737	Non Significant
Creatinine	-0.010	-0.013	0.9562	Non Significant

It is observed that the P value of Comparative A and B group exhibit non significant (>0.05) criterion in various parameters. This means that Group A and Group B have same pharmacological action on the patients.

Parameter (Haematological): Haemoglobin

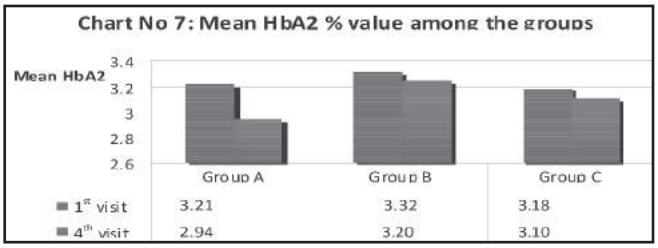


Group A: The mean Haemoglobin was observed in 1st visit was 9.97 and 4th follow up it was 9.98 which was not significant indicating stability in Hb% in this group throughout the study period.

Group B: It is observed that there is no any significant change in mean Haemoglobin level of in this group the mean change in Hb in 1st follow up was 10.46 and in the 4th follow up it was 10.21. In other words Hb% was maintained in group B patients. Though there is no significant change but we can say that Cap SC_3 is having pharmaco-equivalent action as of Group A (Folic Acid)

Group C: Mild elevation is noted in mean Haemoglobin level in this group from 1st follow up 9.95 gm% to 10.16 gm% in 2nd follow up. In 3rd (10.006) and 4th (10.03) follow ups the values show no any significant change. Though there is no significant change in mean Hb% but we can say that Cap AYUSH-RP is having pharmaco-equivalent action as of Group A (Folic Acid).

Parameter (Haematological) : HbA_2%



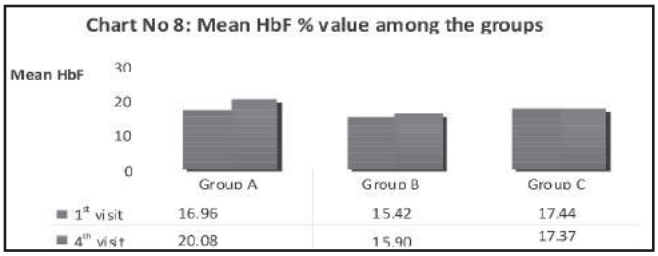
Mean HbA2 %	Group A	Group B	Group C
1st visit	3.21	3.32	3.18
4th visit	2.94	3.20	3.10
Change	-0.27	-0.12	-0.08

From the above chart, it is observed that there is no significant change found in Mean HbA2 of the patients after 4th follow up among different groups. Also the change in the Mean HbA2 found decreased in all groups 4th visit

.Parameter	HbA2	Parameter	HbA2	Parameter	HbA2
Group A - Mean	2.94	Group A - Mean	2.94	Group B - Mean	3.20
Group B - Mean	3.20	Group C - Mean	3.10	Group C - Mean	3.10
Combined Variance	0.39	Combined Variance	0.38	Combined Variance	0.42
SD	0.63	SD	0.61	SD	0.65
SE	0.16	SE	0.16	SE	0.17
Mean Difference	0.25	Mean Difference	-0.06	Mean Difference	0.20
unpaired t value	1.57	unpaired t value	-0.38	unpaired t value	1.18

By observing above t score, it is said that all groups are showing equal response to the treatment of respective group's formulations. In other words, there is no significant change found in said parameter in different groups.

Parameter (Haematological) : HbF%



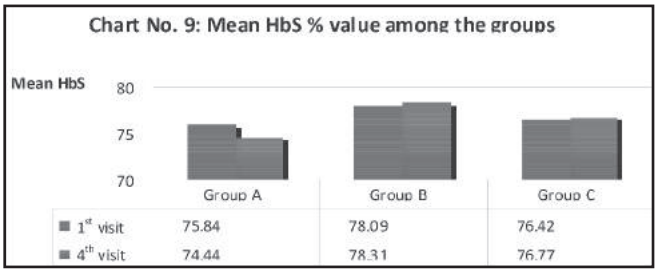
Mean HbF%	Group A	Group B	Group C
1st visit	16.96	15.42	17.44
4th visit	20.08	15.90	17.37
Change	3.12	0.483	-0.07

From the above chart, it is observed that there is no significant change found in Mean HbF of the patients after 4th follow up among different groups. But the change in the Mean HbF found increased in group A by 3.12 while that of in other groups found negligible change 4th visit.

Parameter	HbF	Parameter	HbF	Parameter	HbF
Group A - Mean	20.08	Group A - Mean	20.08	Group B - Mean	15.90
Group B - Mean	15.90	Group C - Mean	17.37	Group C - Mean	17.37
Combined Variance	102.50	Combined Variance	112.61	Combined Variance	27.40
SD	10.12	SD	10.61	SD	5.23
SE	2.61	SE	2.74	SE	1.35
Mean Difference	-4.18	Mean Difference	2.72	Mean Difference	-1.46
unpaired t value	-1.59	unpaired t value	0.99	unpaired t value	-1.08

All the groups are showing equal response to the treatment of respective groups formulations. In other words, there is no significant change found in the said parameter in different groups at 4th follow up.

Parameter (Haematological): HbS%



From the above chart, it is observed that there is no significant change found in Mean HbS of the patients after 4th follow up among different groups. But the change in the Mean HbS found decreased in group A by 1.4 while that of in other groups found increased change 4th visit.

Parameter	HbS	Parameter	HbS	Parameter	HbS
Group A - Mean	74.44	Group A - Mean	74.44	Group B - Mean	78.31
Group B - Mean	78.31	Group C - Mean	76.77	Group C - Mean	76.77
Combined Variance	99.71	Combined Variance	108.62	Combined Variance	22.96
SD	9.98	SD	10.42	SD	4.79
SE	2.57	SE	2.69	SE	1.24
Mean Difference	3.87	Mean Difference	-2.32	Mean Difference	1.55
unpaired t value	1.50	unpaired t value	-0.86	unpaired t value	1.25

By observing above t score, it is said that all groups are showing equal response to the treatment of respective groups formulations. In other words, there is no significant change found in the said parameter in different groups at 4th follow up. But t score between group B and group C shows 1.25, indicating significance if significance level increased i.e. type I error or alpha error.

Result and Discussion

The data was divided in to three sets one as control and other two as trial drugs. The aim was to study the efficacy, safety and tolerability of the trial drug with the comparator as a symptomatic treatment. When the data (mean difference) of trial groups was compared with the control group and the trial groups (Group A and B, Group A and C). Also a comparison was made by between the trial groups (Group B and C). The P values of all the groups for all variables appeared non significant.

While comparing the trial drug Group B & C with the control drug we have found it has similar action as that of Folic acid with respect to haematological parameters indicating that it has similar pharmco-equivalent action as that of control group i.e. folic acid. We compared ayurvedic medicines SC_3 and AYUSH-RP with Folic acid supplementation. The trial group patients did not

receive any folic acid.

Non inferiority of the trial group in relation to control group (folic acid) may argued to be due to storage of folic acid in the liver. However folate stores in human body is easily depleted by 3 to 6 months if folate is not given from outside. Ayurvedic medicine (Group B) was tested for folic acid and was found to be devoid of it. More over a patient with SCD need much higher level of folic acid for replacement. It is convincible that thus beneficial effect of group B and C medicine was not due to any folate like compound in it but due to some yet unidentificable mechanism. Further studies are needed to find out this mechanism by different techniques.

In each group 30 subjects were enrolled. The following observations were noted in three groups. In group A (folic acid) 9 patients were totally without pain at the end of study period in which 3 cases had no any complaint throughout the study period. In group B (SC3) 14 patients are totally without pain at the end of study period. In group C (AYUSH RP) 13 patients are totally without pain at the end of study period; hence we can say that the trial drugs of Group B and C improves quality of life of SCD patients.

In clinical parameters pain it was found that Group B shows marginal better results as compared to Group A & C. This may be due to the immuno-modulatory (Rasayan) effect of the drug. The poly herbal preparation SC_3 contains Bilwa which improves Rakta-Dhatvagni; Drugs like Guduchi, Bhumyamalaki, Kumari, Sharpunkha, and Bhringraj are known to have action on liver and spleen as per Ayurvedic methodology. So it may be possible to have an action on RBC morphology by which it prevents the hypoxic condition and subsequent vaso-occulsive crises, the main cause of pain in SCD.

It may be argued that if none of the estimated laboratory parameters changed significantly on this medication then how can we rationally say the poly-herbal combinations has been effective for this condition. It may not be out of place to mention here that the Ayurvedic preparation used have known anti-inflammatory ingredients and pain is one of the cardinal features of inflammation, here pain relief could have happened with this medication due to its anti-inflammatory activity.

Pallor was found to be decreased in all groups but was not significant. Icterus (yellow sclera) was marginally increased but not significant in all groups.

Considering the safety parameters like Serum Protein, Albumin, Globulin, Blood urea level and Serum Creatinine were within normal limits of all the three groups throughout the study period also Serum Bilirubin (which is usually 3-2 times more in than normal level in case of sickle cell anaemia patients) did not show significant alteration throughout the study period. Indicating that these drugs are safe and having no any hepatotoxic, nephrotoxic, haemaotoxic effect.

Conclusion

In the present study it is observed that, patients from all three groups in general had lesser painful crises, no need for blood transfusion and no iron overload with the medication. However the parameters of hemolysis and increased neurophil count which is normally present in symptomatic SCD patient was also absent. Thus we can conclude that the Ayurvedic drug (SC_3 and AYUSH-RP) may have pharmaco-equivalent action as that of control group (Folic acid).

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ORIGINAL ARTICLE

The Effect of Health Education on Knowledge of Breast Feeding; among Young Female College Students from Mangalore, Karnataka, India

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ABSTRACT

Background: Breast-feeding is the normal way of providing young infants with the nutrients they need for healthy growth and development. Mothers can breastfeed, provided they have accurate information, and the support of their family, the health care system and community at large. Hence an observational study is conducted to assess the effectiveness of health education on knowledge of Breast Feeding **Methods:** With a participatory approach, half day seminar was organized on "Breast Feeding Promotion**"** for young women from Besant's Women College for Arts and Commerce, Mangalore, Karnataka, India. Based on the sessions, predesigned, semi-structured tool (with 14 objective type and 2 open ended questions) was prepared. After prior verbal consent, 340 participants were exposed to Pretest before the seminar. After a week, post-test was done with the same tool. Data was analysed using MC Nemar chi square test & paired t test by SPSS version17. $P<0.05$ was considered to be significant.**Results:** Paired t testshowed mean post-test knowledge score is significantly higher ($P< 0.0005$) than that of Pre-test. For all questions except one, greater number of participants responded correctly in post-test; with 61.5% of answers showing statistically significant increase ($P<0.05$). 26.5% of respondents understood advantages of early breast feeding (colostrum) during post-test as against only 3.2% in pre-training.

Conclusion: Health education on Breast Feeding found to be effective in instilling correct knowledge among college-going women.

Key words: Breast feeding, effectiveness, pre-test, post-test, advantages, knowledge score.

Introduction

Early initiation of breastfeeding contributes to reducing overall neonatal mortality by around 20 per cent, yet only 39 per cent of newborns in the developing world are put to the breast within one hour of birth. [1] India is home to maximum number of under-five deaths and underweight children in the world. [2]

There has been significant evidence produced over recent years to show that breastfeeding is a major contributor to public health and has an important role to play in reducing health inequalities even in the industrialized countries of the world. [3] Breast feeding provides significant values to infants, mothers and the society. Breast fed babies are less likely to suffer from range of serious illnesses like gastroenteritis, respiratory infections and otitis media. [2,4,5,6] Protective effects of breast feeding in infancy may extend to later life, with reduced risk of obesity and chronic diseases.[7] Breast feeding promotes faster maternal recovery from childbirth and reduces risk of breast cancers and ovarian cancers among breast fed mothers in later life. [4,5]

The World Health Organization's "*Global strategy on infant and young child feeding"*states that while breastfeeding is a natural act, it is also a learned behavior and therefore "accurate information should be provided through schools and other educational channels to promote greater awareness and positive perceptions". [8]

Breast feeding promotion is always seen in two dimensions—time (from pre-pregnancy to weaning) and place (the home, community, health care system etc), but third neglected dimension is communication. [9] Communication is an essential part of protecting, promoting and supporting breastfeeding. [9] New lines of communication are being created every day, and we have the ability to use these information channels to broaden our horizons and spread breastfeeding information beyond our immediate time and place to

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activate important dialogue. In this context, this study was conducted to assess the effectiveness of health education on the knowledge of breast feeding; for young women from a Women's College for Arts and Commerce, Mangalore, Karnataka, India.

Methods

This was a quasi- experimental study with pre and post test design; conducted by measuring the effective knowledge score concerned with breast feeding. The health education sessions were organized on "Breast Feeding Promotion" at a Women College for Arts and Commerce, Mangalore, Karnataka, India in first week of August 2012.The second year students of Bachelor of Arts (B. A.)and Bachelor of Commerce (B. Com.)were involved .There were 90 students in each class of second year BA and second year B Com and there were two classes for each course . All 360 students were invited for the health education; however 168 students from second year BA and 172 students from second year B Com were present for the health talk. These 340 participants gathered together in a college hall. Before the actual health talk, the participants were exposed to the self administered questionnaire, after their prior verbal consent; to record pretest knowledge. Data was collected by a predesigned, semi-structured questionnaire tool (with 14 objective type and 2 open ended questions). The contents of the questionnaire included "when to start breast feeding in all types of deliveries and what are the advantages to start early, how long to breast fed baby, what is exclusive BF and how long to give exclusive BF; what is weaning and whether to continue BF even during weaning; what are the overall advantages of BF both to the baby and to the mother" This tool was validated before application for this study. During a health talk participatory approach was adopted, there was free discussion and the participants clarified their doubts. After a week, all the participants were subjected to the same tool to record the post-test knowledge. For knowledge score, all the 16 questions in the questionnaire were assigned one mark each. The correct response for each question was awarded one mark and the wrong answer was awarded zero mark. (negative marking was not considered). Overall total score of each participant was calculated and used for application of Paired T test. We compared the frequency of pre test knowledge (based on correct /wrong response. ie Correct response - knowledge present and Wrong response- knowledge absent) &Post test knowledge one week after giving health education. As we compared qualitative response of pre test&post test knowledge, we applied Mcnemar chi square test to measure the effective increase (or otherwise) in knowledge regarding breast feeding. For analysis,Statistical Package for Social Sciences (SPSS) version17 was used. $P<0.05$ was considered to be significant.

Results

A total 340 young women between 18 years (minimum) to 22 years (maximum) of age participated in the health education sessions on Breast-Feeding (BF) and correct BF practices. The participants' mean age (SD) was 19.09 (0.814) years. Majority of them were unmarried (88.2% -300/340). Religion wise distribution showed 49.7% Muslim, 45.3% Hindu and 5% Christian. Mean post-test knowledge score was significantly higher ($P < 0.0005$) than that of the pre-test, as seen after application of paired t test in Table 1.

Table 1: Knowledge Scores in Pre and Post training evaluation– paired t test

Breast feeding knowledge	Mean	Std. Deviation	Std. Error Mean	Mean diff	95% CI of Mean diff	p
BFK pre test	9.58	4.932	0.271	2.130	1.559 to 2.702	<0.0005
BFK post test	11.71	2.656	0.146			

* $P< 0.0005$Significant

In this study, 26.5% (90/340) of the participants understood the advantages of early BF (colostrum) after the health education sessions as recorded in the post-test proforma, as against 3.2% (11/340) before the sessions.

Table 2: Distribution of respondents according to Knowledge Scores of advantages of breast-feeding- in Pre and Post test

Advantages of BF	Pre test Respondents* (%)	Post- test Respondents *(%)
Baby remains healthy.	271(79.7)	293(86.2)
Proper growth of baby	16(4.7)	22(6.5)
Helps in bonding with mother+	7(2.1)	25(7.4)
Baby's health	46(13.5)	----
Total	340(100)	340(100)

*Respondents giving correct answers as YES

Increased knowledge score in each of the recorded advantages of the colostrums in post test responses mentioned in the Table 3, was found to be highly significant (P < 0.0005).This indicates the effectiveness of the health education sessions for this component.

Table 3: Distribution of respondents according to Knowledge Score of advantages of colostrum –Pre and post test

Reason for not discarding colostrums	Pre test Respondents (%)	Post- test Respondents (%)
Reason not mentioned	329(96.8)	250(73.5)
Contains antibodies	2(0.6)	20(5.9)*
Good for health of baby	4(1.2)	40(11.8)*
Provides nutrients & increases immunity	5(1.5)	30(8.8)*
Total	340(100)	340(100)

McNemar chi- square test.*P<0.0005 Significant

Various other contents of the health education sessions are included in the table 4 which highlighted the fact that greater number of participants responded correctly in post test evaluation done after a week of the actual sessions. The post test score was higher among 92.86 % (13/14) of the variables. This post-test increase in their score was statistically significant for 61.5% variables (8/13) with higher post test score. viz; early BF initiation in all including operational deliveries, feeding colostrum, complementary feeding after 6 months along with the BF and other BF variables related to the correct knowledge as mentioned under serial no 7, 8, 9, 13 of the Table 4.

Discussion

1In light of extensively studied benefits of breast feeding to the society, mother and the infant [10, 11] it has been estimated that the lives of one million infants a year can be saved in the developing world by promoting breast feeding. Different factors affecting such promotion may include mothers' awareness, socio-economical factors and more importantly health professional's training and attitude [12] .In the year 2012, on occasion of World Breast Feeding Week, health talk on breast feeding promotion was organized by the author, for young female students (18 to 22 years of age) of one of the women's college at Mangalore, South Karnataka District, India and the effectiveness of this activity was studied. Because the decision to breast-feed is often made long before a woman becomes pregnant, breast feeding promotion strategies should focus on educating the women during their preconceptional years. [13] Studies of non-pregnant high school students suggested that attitude towards infant feeding begin to form well before pregnancy.[14,15] It is also reported that the adolescent girls who had more knowledge and positive attitude towards breast feeding were more likely to consider breast feeding. [15, 16, 17]

The breast feeding is one of the oldest practices followed by all religions and it is universally endorsed solution in the prevention of early malnutrition; [18]. Early initiation of BF has a significant advantage of being colostrum rich breast milk. However, in this study 96.8 % (329 out of 340) participants were not aware of the advantages of colostrums feeding (before the health education). Misinformation among adolescents regarding breast feeding is widespread. [19]A survey of 100 teenage females in suburban Massachusetts [20] showed that they were also not certain whether breast feeding was beneficial to newborns and nursing mothers; hence Leffler , the author of the study, concluded that the teenage girls should be targeted for breast feeding education. [20]

In this study, initially before the health education 62% of women were of opinion that BF should be started within one hour of normal delivery and 30.6 % responded for the same for women after caesarian section (Table 4) .After the health education, the post test knowledge score for the same variables showed highly significant increase from 62 % to 89.7% and 30.6 % to 70.9% respectively (P< 0.0005). In a Jordan study [21] conducted by McDivitt et al (1993), aiming to examine the role of mass communication in increasing timely initiation of BF after a birth in Jordan, reported that knowledge about initiation of BF within 6 hours of birth increased from 51 % to 75%.[21]

There was marginal increase (from 75.6% to 77.6%) in the response for the variable “Exclusive BF should be

given up to 6 months to the baby" in this study.During breastfeeding nutrients and antibodies pass to the baby and the maternal bond can also be strengthened .[22] In this study, after health education on BF promotion, college girls showed increased knowledge score in general advantages of BF and advantages colostrums (Table2 and 3) as recorded by 3.2% before the health education to 26.5% after the health education. In a Pakistan study Colostrum related myths were also addressed in a college, where only 36% girls were sure to feed their baby the 1st milk.[23] In this study, 90% of the participants responded positively after the health education (as against 75.6% before) to the fact that "BF will increase the attachment between the mother & the child" (P<0.0005, Table4).

In this study, though 67.6 % women were already aware before the health education, of the message that 'by initializing breast feeding within 1hour- it helps the uterus to get back to normal shape'; the percentage had increased to 85.3% after the health talk (P<0.0005, Table4).

During the health talk it was also addressed that even if there are twins, the breast milk is sufficient for both (Table 4). For this message, post training response (78.2%) was more than the pre-training response (67.6%) (P=0.004). The breasts can respond to the demand and produce large quantities of milk. Some mothers have been able to breastfeed triplets successfully. [24]

In an Indian study conducted at Srinagar, by Bhat et al [25] it was reported that the mothers, whose infants were well nourished, had a higher level of breast feeding knowledge than did those whose infants were moderate to severely malnourished (score, 27.13 vs. 16.01-18.75; P <0.0001). None of the mothers of malnourished infants (from same study) had good score on breast feeding practices. The findings of this Srinagar study showed a decreasing trend between awareness and practice of BF / infant weaning, suggesting that further improvement of health education was needed to reduce the lag between breast feeding awareness and practice. [25]

Health education is an important component for breast feeding promotion strategy. In this study, health education towards breast feeding promotion, to young college girls found to be effective in enhancing their correct knowledge related to breast feeding. However, in future, similar type of activity during their pregnancy can make greater impact towards following correct breast feeding practices.

Table 4: Distribution of respondents according to Pre and Post test Knowledge Scores for variables of breast feeding behavior

Positive response (Yes) as correct answers (one mark for correct answer for each variable)	Knowledge assessment, n=340		P Value
	Pre test Respondents (%)	Pre test Respondents (%)	
1. After normal delivery breast feeding should be started within 1hr	211(62.1)	305(89.7)	<0.0005*
2. Even after caesarean, breast milk should be given within 1hr	104(30.6)	241(70.9)	<0.0005*
3. Should the thick yellow colored milk which comes from the breast initially called " colostrum" be given to baby	193(56.8)	242(71.2)	<0.0005*
4. Exclusive breast feeding should be given upto six months to the baby	257(75.6)	264(77.6)	0.589
5. After 6 month, baby can be fed with other soft food (weaning) along with breast feeding	245(72.1)	271(79.7)	0.017*
6. Breast feeding should be continued at least upto 2yrs	78(22.9)	101(29.7)	0.06
7.By initializing breast feeding within 1hr it helps the uterus to get back to normal shape	230(67.6)	290(85.3)	<0.0005*
8.Breast feeding the baby will increase the attachment between mother & child	257(75.6)	306(90)	<0.0005*
9. Even if there are twins, the breast milk is sufficient for both.	230(67.6)	266(78.2)	0.004*
10.Mother should not fall asleep while breast feeding	273(80.5)	277(81.7)	0.773
11. While mother is ill, she cannot breast feed her child	221(65.2)	230(67.8)	0.541
12. Other fluids should NOT be given to baby after delivery	187(55)	171(50.3)	0.250
13. Regular breast feeding will NOT spoil the looks of the breast	191(56.2)	261(76.8)	<0.0005*
14. After delivery mother should NOT eat less food	219(64.4)	240(70.6)	0.085

*P<0.05 Significant

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CASE REPORT

Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) Syndrome Induced by Anti-tuberculosis Drugs

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ABSTRACT

DRESS syndrome is a life-threatening pattern of a drug hypersensitivity reaction. The syndrome's complete form combines a severe febrile skin eruption (usually the first sign), hyper-eosinophilia, atypical lymphocytes, and organ involvement, such as hepatitis, myocarditis, interstitial nephritis, and interstitial pneumonitis. Lymphadenopathy and hepato-splenomegaly may be present, as may arthritis and synovitis.

This idiosyncratic reaction occurs most commonly after exposure to drugs such as allopurinol, sulfonamides, and aromatic anticonvulsants such as phenytoin, phenobarbital, and carbamazepine. We report 19 year old male taking antituberculosis drugs for spinal tuberculous osteomyelitis for 2 months. Our patient's clinical manifestations included fever, lymphadenopathy, rash, eosinophilia, and visceral involvement (hepatitis and pneumonitis). Our patient was diagnosed as DRESS syndrome with peripheral blood smear showing eosinophilia and atypical lymphocytes; which responded to stopping the anti tuberculosis drugs. After complete resolution of all symptoms, patch test was positive for rifampicin.

Case Report

A 19 year old male, a diagnosed case of spine tuberculous osteomyelitis, had fever and pain in abdomen since 15 days. He also perceived yellowness of eyes since 4 days. Fever was present mostly in afternoon and was associated with chills and rigors and with sweating and rash all over body. There was loss of appetite due to nausea and he had vomiting 7-8 episodes per day. He suffered mild pain in abdomen in epigastric region. He was taken to a private hospital 4 days back and diagnosed to have Dengue IgM positive. He was referred to Sassoon general hospital for further management. He had good urine output and no respiratory complaints. The patient had been taking cat I AKT since 2 months. AKT was changed and he was given liver sparing drugs ethambutol, streptomycin, levofloxacin since 4 days. There was no history of drug rash in immediate family.

On examination the patient was conscious orientedand febrile with deep icterus. Rash was present all over body exanthematousin type. A single lymph node was palpable in right cervical region 2cmX2cmtender to touch. There was no matting. Tender hepatosplenomegaly was noted. Rest of the systemic examination was within normal limit.

On routine investigation, patient had deranged renal function tests and liver function tests. He had a platelet count of 3,34,000 and ESR of 35. Peripheral smear had a total leukocyte count of 50,000 with an absolute eosinophil count of 20,000 and few atypical lymphocytes. The smear showed no parasites. However, malaria antigen was positive for plasmodia falciparum. Bile salts and bile pigments were present in urine. Chest roentogram revealed right pleural effusion and right middle zone consolidation. Ultrasonography of abdomen confirmed hepatosplenomegaly. On testing hepatitis viral markers, patient was found to be HBsAg positive. However, HBeAg negative and anti HBc IgM negative. Also HBV DNA- was negative by qualitative analysis. Biopsy of cervical lymph nodeshowed reactivelymphadenitis on histopathological examination.

On admission, he was started on Artesunate, Doxycycline and liver sparing anti tuberculosis treatment of Streptomycin, Levofloxacin and Ethambutol. On day 3 he had reaction to streptomycin after test dose, so streptomycin was stopped and Amikacin was started. Rash which was previously exanthematous progressed to become exfoliative with exfoliations seen over face, back and scrotum. Also,

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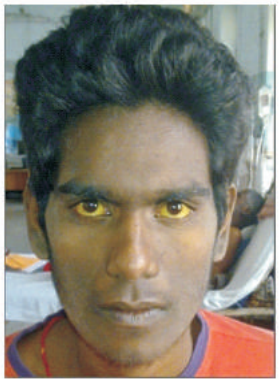
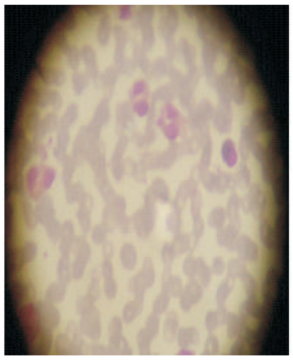
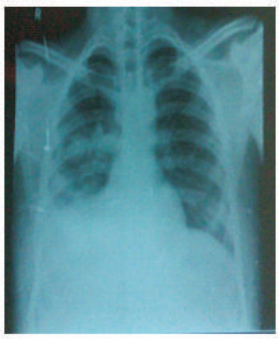
bullae with some central crusting over right hand and bilateral feet were seen. It was thought to be a drug rash with most likely streptomycin which was stopped as described above. Adequate hydration was maintained.

	Day 1	Day2	Day6	Day7
creatinine	1.56	1.8	1	0.9
urea	85	51	58	48
Total bilirubin	3.5	2.5	8.2	9.3
Direct bilirubin	2.5	1.5	6.7	6.8
SGOT	183	192	438	538
SGPT	186	204	578	578

Table 1 showing serial values of renal function tests and liver function tests







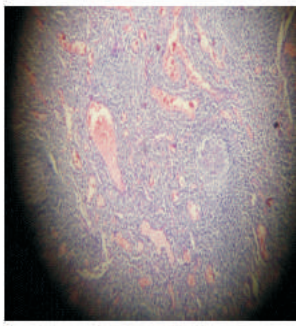


Fig.1 (left upper corner) showing deep icterus

Fig.2 (right upper corner) peripheral blood smear showing eosinophilia

Fig.3 (left lower corner)chest xray showing right middle zone consolidation with right pleural effusion

Fig.4 (right lower corner) lymph node biopsy showing reactive lymphadenitis

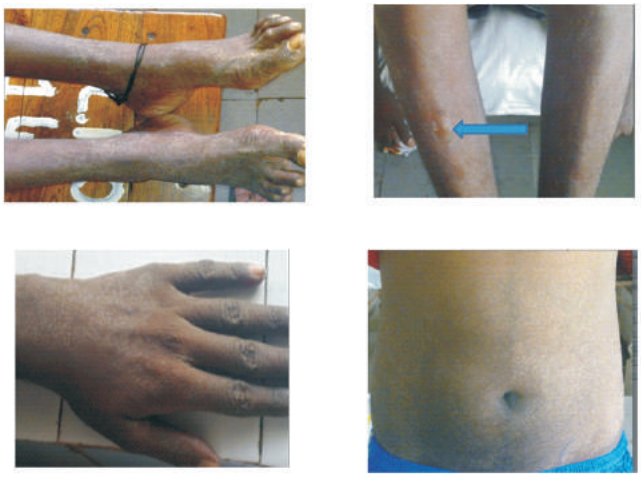


Fig.5 A selection of 4 pictures showing exfoliative dermatitis; with arrow pointing to a bullous lesion on leg

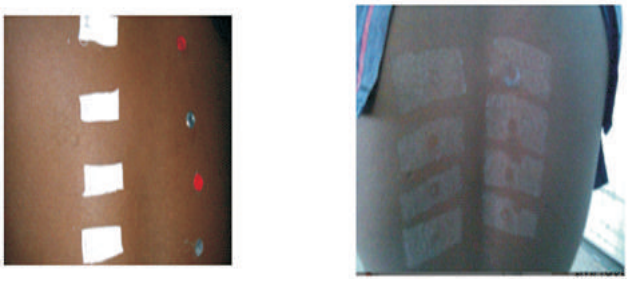


Fig. 6 Patch test done on back of the patient. Right side patches are controls. Left side patches are drugs. Results were seen after 48 hours and 72 hours. From above downwards isoniazid, rifampicin, pyrazinamide and ethambutol were tested. Itching was observed in rifampicin patch.

	Day2	Day3	Day7
TLC	50000	32000	15000
neutrophils	38	35	40
lymphocytes	18	25	25
atypical lymphocytes	Seen	Not seen	Seen
eosinophils	40	40	25
absolute eosinophil count	20000	12800	6000

Table 2 showing serial values in peripheral smear

On day 6 , LFTs continued to have an increasing trend and rash worsened. It was decided to stop all drugs; as the worsening parameters were clinically more likely due to drugs. So, AKT and Doxycycline was stopped. Artesunate was stopped on 7th day.

	Day9	Day10	Day12	Day13	Day18	Day20
creatinine	0.9	0.9	0.9	0.9	1.0	1.0
urea	27	20	20	20	18	22
Total bilirubin	9.7	10.7	12.2	16.0	10.0	7.7
Direct bilirubin	6.7	7.0	7.0	8.5	6.8	5.7
SGOT	732	1132	741	528	140	82
SGPT	600	638	557	475	194	114

Table 3 showing serial values of renal function tests and liver function tests after stopping drugs

	Day12	Day18
TLC	15000	11000
neutrophils	73	70
lymphocytes	25	28
atypical lymphocytes	Seen	Not seen
eosinophils	2	1
absolute eosinophil count	300	110

Table 4 showing serial values in peripheral smear after stopping drugs

In further 10 days, hepatosplenomegaly resolved to become non palpable. Also, liver enzymes and bilirubin had a decreasing trend as shown in table above. Patient regained appetite and icterus resolved to minimal yellowish tinge.

Patch test was done. Itching was in the region where rifampicin was applied. So, the final diagnosis of Drug reaction eosinophilia and systemic symptoms syndrome (DRESS Syndrome) due to AKT(rifampicin) was made.

On day 18, amikacin, levofloxacin, ethambutol were reintroduced and patient was discharged and followed up. The patient continued with the above regimen for about 2 months after which his liver function tests were normal. Slow re indroduction of isoniazid and rifampicin were done.

Now the patient is on the same with no symptoms since 6 months.

Discussion

Drug Reaction with Eosinophilia and Systemic Symptoms(DRESS) was coined by Bocquet et al in 1996. It is a severe life threatening drug reaction which is idiosyncratic and multi-system reaction. It is a clinical triad of fever, rash andinternal organ involvement (e.g. hepatitis, myocarditis, nephritis or pneumonitis) occurring 1 - 8 weeks after medicine exposure (long latency).

The diagnosis of DRESS syndrome requires the simultaneous presence of three criteria :(a) drug-induced skin eruption, (b) eosinophilia ≥ 1.5 x 109/l or atypical lymphocytes, and (c) at least one of the following systemic abnormalities: enlarged lymph nodes at least 2 cm in diameter, hepatitis (transaminases ≥ 2N),interstitial nephropathy, interstitial lung disease, or myocardial involvement. Other synonymous names of DRESS are HHS (Hypersensitivity Syndrome), AHS (Anticonvulsant Hypersensitivity Syndrome),DIHS (Drug-Induced Hypersensitivity Syndrome), DIDMOHS (Drug-Induced Delayed Multiorgan Hypersensitivity Syndrome), and Drug-Induced Pseudolymphoma.

The Fever is a common early feature. Fever preceeds a widespread and long-lasting papulopustular or erythematous skin eruption; which often progresses to exfoliative dermatitis. The severity of the skin-related changes does not correlate with the extent of internal organ involvement, which may remain asymptomatic or be life-threatening. The incidence of DRESS with anticonvulsants has been estimated at 1 in 10,000 exposures.

The skin disease is characterized by an infiltrated maculopapular eruption and facial edema, often more marked in the peri-orbital regions. The lesions develop first on the trunk then spread to the rest of the body. The initial edematous maculopapular lesions convert to blisters, vesicles or pustules. The histological finding lack specificity, consisting mainly of a lymphocytic inflammatory infiltrate and, less prominently, of eosinophils in the papillary dermis. 80% of individuals with DRESS show Hepatic involvement and 40% show Renal affection. Pulmonary and cardiac involvement were 33% and 15% respectively.

Hematological abnormalities were found in 25-63% of cases only. A wide range of drugs were implicated to be responsible for this syndrome.

No proved data on pathophysiology exist till today. The prevailing hypotheses are described below. Defective

detoxification of reactive oxidative metabolites and its accumulation leads to onset of symptoms after long latency. A genetic predisposition and slow acetylator status may contribute. Also, a viral co-infection is suspected; specifically, a reactivation of the human herpes virus 6 (HHV6). Eosinophil accumulation is also thought to account for the internal organ involvement.

Diagnosis is based on clinical presentation (i.e. the triad of fever, rash and organ involvement), supported by a finding of eosinophilia and abnormal liver function tests. A temporal relationship between medicine use and the onset of the syndrome is the most important indicator of causality. Treatment consists of immediate withdrawal of all suspect medicines, followed by supportive care of symptoms. Patients who develop DRESS must avoid re-exposure to the causative medicine/s.

Antipyretics should be prescribed to reduce the effect of fever. Skin care may include the use of topical steroids to alleviate symptoms. In case of exfoliative dermatitis, warming of the environment and correction of electrolyte disturbances should be done. High caloric intake should be encouraged and all precautions are undertaken for prevention of sepsis.

Systemic corticosteroids are generally used in the more severe DRESS cases involving significant exfoliative dermatitis, pneumonitis and/or hepatitis. The effect of corticosteroids on prognosis is unknown as controlled clinical trials are lacking. Relapses may occur as corticosteroid doses are tapered, and treatment may need to be continued for many weeks. Care should be taken as the use of systemic steroids might produce viral reactivation.

High doses of N-acetylcysteine could be beneficial in anticonvulsant drug reactions as it is a known precursor of glutathione, a molecule involved in the detoxification pathway of several drugs including anticonvulsants.

The diagnosis of DRESS should be highly suspected with the presence of skin rash, liver involvement, fever, hypereosinophilia, and lymphadenopathy. Prompt withdrawal of causative drug is mandatory. Steroids play a role in severe DRESS syndrome. Reexposure of drugs should be avoided. Severe drug reaction may be reduced with proper initial dosing and slow dose escalation.

Acknowledgements

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CASE REPORT

Spitz Nevus Arising From Congenital Melanocytic Nevus: A Rare Case Report

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ABSTRACT

Spitz nevus, also known as benign juvenile melanoma, is a rare condition occurring commonly in first two decades of life primarily involving face and lower extremities with slight female predominance. Commonly, Spitz nevus is reported to arise de novo. Here, we report an interesting case of a six year old female with Spitz nevus that arose from congenital melanocytic nevus.

Key Words: Spitz, nevus, melanocytic, melanoma

Introduction

In 1948, Sophie Spitz first described some childhood melanocytic lesions which although resembling melanomas histologically, followed a benign clinical course; hence the term 'benign juvenile melanoma'.[1] Other synonyms for the Spitz nevus include Spitz tumor, juvenile melanoma, spindle cell and epithelioid nevus, and nevus of large spindle and/or epithelioidcells.[2,3]

Case Report

A six year old female child presented with an itchy, painless, rapidly progressive, dark coloured elevated lesion over scalp since three months. She had history of a dark coloured flat lesion at same site since birth. Cutaneous examination revealed solitary dome shaped, reddish, non-tender firm nodule 2x2 cm in diameter with eroded surface overlying a hyperpigmented hairless plaque measuring 5x3 cm on right temporal aspect of scalp (Figure.1).Routine haematological, biochemical and radiological investigations were normal. Differential diagnoses of melanoma, pyogenic granuloma and juvenile xanthogranuloma for nodule; and congenital melanocytic nevus and nevus sebaceous for plaque were considered. Nodule was excised en toto whereas punch biopsy from underlying plaque was

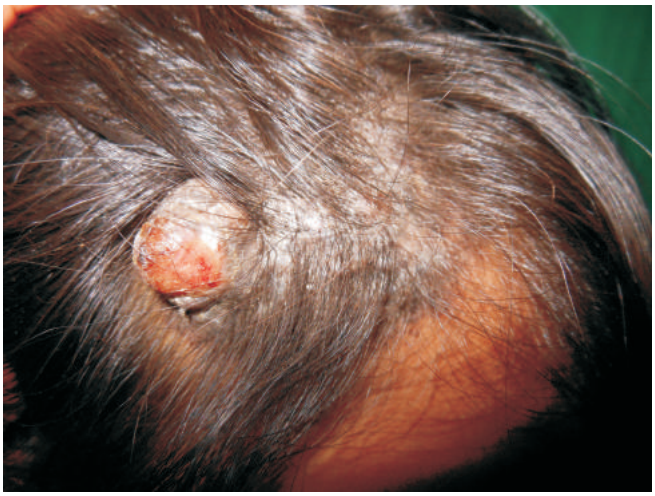

Figure.1-Solitary nodule 2x2 cm in diameter with eroded surface overlying a hyperpigmented hairless plaque measuring 5x3 cm on right temporal aspect of scalp

taken. Histopathological examination of nodule show edepidermal hyperkeratosis, acanthosis, with large epitheloid cells with plump nuclei in the basal layer. Upper dermis showed nests of spindle and epitheloid cells with melanin pigment and aggregates of pathognomonic eosinophilic globular Kamino bodies. Lower dermis showed nests of rounded to oval nevus cells extending into epidermis with signs of maturation towards deeper dermis. Mitotic figures were minimum (Figures.2). Histopathological examination of underlying plaque revealed dermal nests of nevoid cells without atypia or junctional activity suggestive of congenital melanocytic nevus (Figure.3). However, we could not do special stains like HMB-45, melan A in order to confirm the diagnosis, owing to limited resources and non-affordability of the patient. Thus, final diagnosis of Spitz nevus arising from congenital

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melanocytic nevus was made. Nodule was completely excised under local anaesthesia and has not shown recurrence over a follow up period of six months (Figure.4).

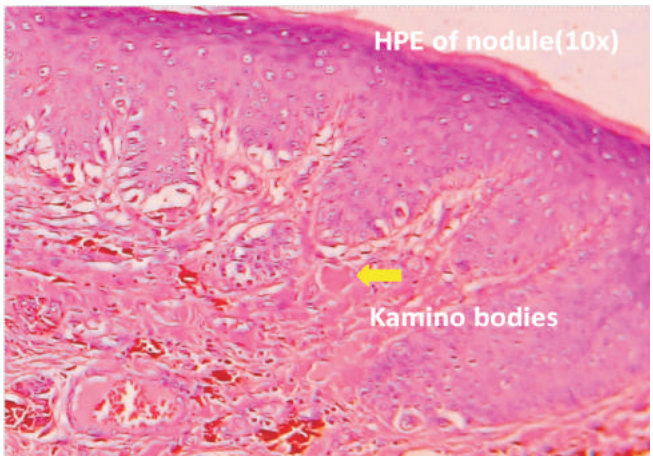

Figure.2- Nests of spindle and epitheloidcells, and Kamino bodies in upper dermis on hematoxylin and eosin stain at 40x magnification suggestive of Spitz nevus

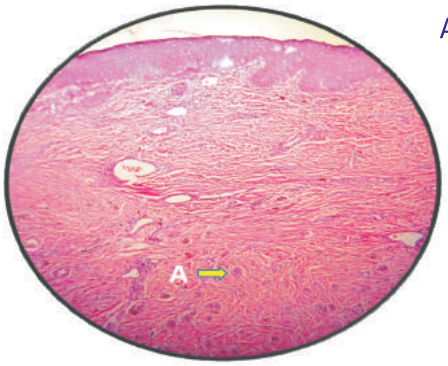

Figure.3- Nests of nevoid cells without atypia or junctional activity on hematoxylin and eosin stain at 10x magnification suggestive of congenital melanocytic nevus

Table.1- Clinical, histopathological and immunohistochemical attributes of classic Spitz nevi and atypical Spitz tumors. (Adapted from Luo S, Barnhill and Spatz et al)

	Classic Spitz nevi	Atypical Spitz tumors
CLINICAL FEATURES		
Age	<10 years	>10 years
Location	Face, neck, extremities	Back
Size	<5 mm in diameter	>10 mm in diameter
Shape	Symmetric, dome-shaped	Increasing asymmetry
Border	Well-demarcated	Irregular
Surface	Smooth	Irregular, ulcerated
Color	Reddish pink	Irregular
HISTOPATHOLOGY		
Organization	Orderly, nondisruptive	Haphazard, infiltrative
	Symmetric	Asymmetric
	Sharply demarcated	Poorly circumscribed
	Intact, hyperplastic epidermis	Disrupted, ulcerated epidermis
	Aggregates of Kamino bodies	Absent or few Kamino bodies
	Lack of deep involvement	Subcutaneous involvement
	Zonation: side-to-side uniformity	Lack of zonation
	Smaller nests with depth	Persistent, expansile deep nests
	Limited pagetoid spread, lower epidermis	Prominent, single cell pagetoid spread, beyond epidermal nests
Proliferation	Mitoses <2/mm^2	Mitoses >2-6/mm^2
Cytology	Spindled or epithelioid cell type	More heterogenous cell types
	Ground glass or opaque cytoplasm	Granular, dusty cytoplasm
	Low nuclear to cytoplasmic ratio	High nuclear to cytoplasmic ratio
	Uniform nucleoli	Large, eosinophilic nucleoli
IMMUNOHISTOCHEMISTRY		
Ki-67	Stains fewer cells	Stains greater percentage of cells
HMB-45	Prominent in superficial aspects of classic Spitz nevi	Stains both superficial and deeper dermal level

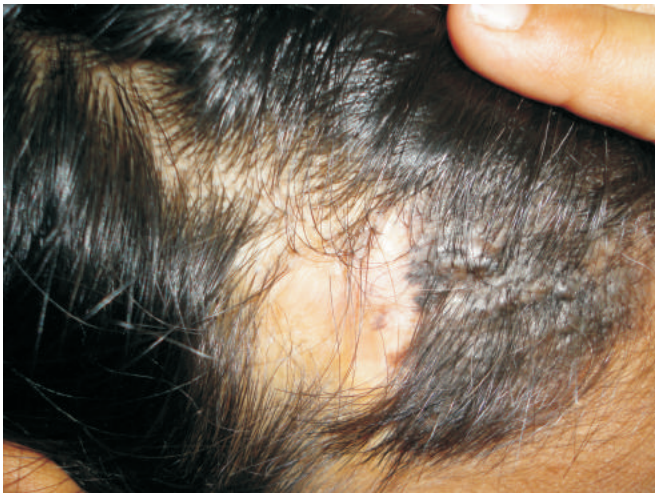

Figure.4- Post excision follow up

Discussion

Spitz nevi are melanocytic proliferations characterized by spindled and/or epitheloidnevomelanocytes.[4] Although difficult to document, Herried et al have approximated an incidence of seven per lakh population.[5]Classical Spitz nevus presents as well circumscribed small to medium sized firm pink to flesh coloured papules with smooth discrete border predominantly involving face and legs. Lesions usually grow rapidly over a period of 3–6 months, after which they may remain static for many years.[6] Bleeding and crusting that can occur after minor trauma due to thin overlying epidermis, may lead to diagnostic confusion with pyogenic granuloma, as was in our case.

Variants of Spitz nevus that have been reported are spindle cell naevus of Reed, *multiple Spitz naevi, Agminate Spitz naevi,* desmoplastic Spitz naevus.[6,7]Most commonly, a classic Spitz nevus exhibit 'starburst pattern' on dermoscopy.[6]

Today, contrasting opinions exist regardingbenign versus malignant nature within the spectrum of Spitz tumors which include Classic Spitz naevus, Spitzoid melanoma and 'Atypical spitzoid tumour of unknown malignantpotential' (ASTUMP). Because of the frequent diagnostic difficulty in classifying these lesions, histologic evaluation of the entire lesion is mandatory. Table-1 highlights clinical, histopathological and immunohistochemical attributes of classic Spitz nevi and atypical Spitz tumors.[4,8,9]

Classic Spitz nevi are best excised locally with a narrow margin of 1–2 mm of normal skin; whereas for atypical Spitz tumors, margin of excision should be as for melanoma: 1 cm for tumors of less than 2 mm in thickness; 2 cm or more where the thickness is 2 mm or greater.[6]However, recurrence rates as high as 7% to 16% have resulted from incompletely excised lesions.[10] Hence, complete excision with margins free of tumor, especially for lesions with any atypical features (clinically or histologically) or Spitz nevi in adults, has been recommended. Patients with atypical lesions need to be followed up regularly every 6 to 12 months.[7]Our case revealed benign Spitz histology, but arose from a large congenital melanocytic nevus (diameter <20cm), which itself carried risk for malignant transformation albeit marginal. Maximum benefit would have been achieved with excision of entire lesion including plaque, which however, could not be done owing to its larger diameter. Hence, the patient is being followed up regularly for recurrence or malignant transformation.

A Spitz nevus can arise de novo, however there are rare cases reported of it arising from, Speckled lentiginousnevus (nevus spilus),[11]Glomuvenous malformation[12] and Congenital compound nevus pigmentosus.[13] So also, congenital melanocytic nevi, especially the giant ones (diameter≥ 20 cm), pose a definite risk for malignant melanoma. In addition, a rapidly growing, ulcerative tumour arising from congenital melanocytic nevus called nodular proliferative neurocristichamartoma has been described at birth.[14]A case of nodular lesions arising in a large congenital melanocytic nevus in a newborn with eruptive disseminated Spitz nevi has been reported.[15]In our case, however, Spitz nevus arose from a congenital melanocytic nevus.

To the best of our knowledge, a case of Spitz nevus arising from a congenital melanocytic nevus; so also a congenital melanocytic nevus transforming into Spitz nevus, is *hitherto* unreported.

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CASE REPORT

Subcutaneous phaeohyphomycosis at an unusual site

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ABSTRACT

Phaeohyphomycosis is a deep fungal infection caused by dematiceous fungi commonly affecting the trauma prone sites such as arms and the legs. We report a case of unusual truncal involvement in a 50 yr old immunocompetent female farmer.

Introduction

IPhaeohyphomycosis (phaemycotic cyst, cystic chromomycosis) is a rare and generally localized, subcutaneous or intramuscular infection caused by a range of brown-pigmented (dematiaceous) fungi including Exophiala jeanselmei, Exophiala dermatidis, Bipolaris, Alternaria species and others that form pigmented hyphae in tissue. It includes a wide spectrum of infections varying from cutaneous, subcutaneous, cerebral and systemic opportunistic infections. Cutaneous involvement presents as well-encapsulated, subcutaneous nodules or cysts which may ulcerate to discharge pus.

Case Report

A 50 year old female farmer presented with gradually progressing multiple painful crusted raised lesions which ruptured to discharge pus over back, chest, left side of neck since 10 years. Past history of minor thorn-prick injury was ellicited. No history of discharge of granules, evening rise fever, chest pain, breathlessness or weight loss was evident. History did not reveal any other pre-existing medical illness or surgical intervention. Clinical examination revealed multiple skin coloured to erythematous firm tender crusted nodules, few of them ruptured to discharge pus admixed with blood at places, with bridging scars over left supraclavicular area, mammary area and back. (Figure.1a,b) Non tender, non matted axillary and inguinal lymphadenopathy was present. Systemic examination was unremarkable. Clinical differential of scrofuloderma, cutaneous actinomycosis, atypical mycobacterial infection and deep fungal infection was kept.

Baseline laboratory investigations revealed presence of anemia (10 mg%) and raised erythrocyte sedimentation rate (45mm at the end of 1 hour), a normal blood sugar profile, renal and liver function test , negative ELISA test for HIV. Chest X-ray was not suggestive of underlying foci of tuberculosis and Mantoux test was negative. A 10% KOH mount done from one of the discharging sinus revealed presence of broad septate brown pigmented fungal hyphae. (Figure. 2)

Biopsy done from two crusted nodular lesions showed presence of focal ulceration with suppurative granulomatous infiltrate consisting admixture of neutrophils, lymphocytes, plasma cells, epithelioid cells and foreign body giant cell involving the mid and lower reticular dermis extending into the panniculus on hematoxylin and eosin stain. (Figure. 3) Periodic acid Schiff stain and stain for acid fast bacilli were negative. Cultures for tubercular bacilli and fungi were also negative. Ultrasonographic examination of the chest showed soft tissue foci of collection without involvment of the underlying bone or organs suggesting an infective etiology. Ultrasonography of the abdomen and pelvis were within normal limits.

On the basis of positive KOH mount and literature review a diagnosis of subcutaneous pheohyphomycosis was made and the patient was started on oral itraconazole 200mg twice a day daily dose. Four months follow-up with monitoring of liver function test showed about 40% resolution of the suppurative granulomatous infiltrate consisting admixture of neutrophils, lymphocytes, plasma cells, epithelioid cells and foreign body giant cell involving the mid and lower reticular dermis up of most of the sinuses and reduction in

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discharge and size of the nodulo-ulcerated lesions. (Figure.4)

Discussion

Phaeohyphomycosis is the name given to those subcutaneous and systemic diseases caused by various brown moulds that develop in tissue in the form of dark walled septate mycelium.[1]These fungi have been recovered from soil, wood, and other plant materials. Subcutaneous phaeohyphomycosis typically results from the traumatic implantation of the aetiological agents. The disease process usually results in a subcutaneous abscess or a cystic granuloma.

Microscopically, the aetiological agents present as yeast elements, pseudo-hyphae, septate hyphae, ramified hyphae (short or long; regular or curled) or a combination of these findings with a brownish colouration.[2] The main genera involved include *Alternaria, Bipolaris, Cladophialophora and Exophiala*.[3]

E. jeanselmei is expected to be the main aetiological agent of subcutaneous phaeohyphomycosis due to its wide presence in nature. *C. bantiana* is expected to be the aetiological agent of systemic phaeohyphomycosis with brain damage due to its favourable neurotropism. *C. gloeosporioides* was an unexpected finding as the cause of subcutaneous phaeohyphomycosis in a patient with a transplanted lung. However, in recent years, five species of the *Colletotrichum* genus have been reported as agents of human infections.[4]

Phaeohyphomycosis can be distinguished from two other subcutaneous mycoses caused by phaeoid fungi: Chromoblastomycosis and Mycetoma. The differential diagnosis is established by the presence of muriform cells (sclerotic bodies) or black grains in cases of chromoblastomycosis and mycetoma, respectively.[5]

The diagnosis is made by the finding of dematiaceous fungal elements in tissue.6 by direct microscopic examination and histopathology. The fungal hyphae are best visualized with such fungal stains as Grocott's methenamine silver stain. The various agents of subcutaneous or systemic phaeohyphomycosis in tissues are so similar in appearance that they cannot be differentiated solely on the basis of morphology. Culture is always needed for a specific identification of the aetiological agents.[6]

Our patient lived in a rural area and had a history of thorn prick injury which could have favored inoculation of the fungi. However, truncal involvement seen in our case is little unsual as most common sites of involvement are the leg and foot Dematiaceous fungi may have unique pathogenic mechanisms owing to the presence of melanin in their cell walls. It is thought to be a virulence factor by conferring a protective advantage, scavenging free radicals and hypochlorite that are produced by phagocytic cells and normally kill most organisms [1, 7].Clinically, most presentations are localized skin infections typically occurring on exposed areas of the body, especially the arms and legs, resulting from traumatic inoculation [1, 8, 9, 10, 11].

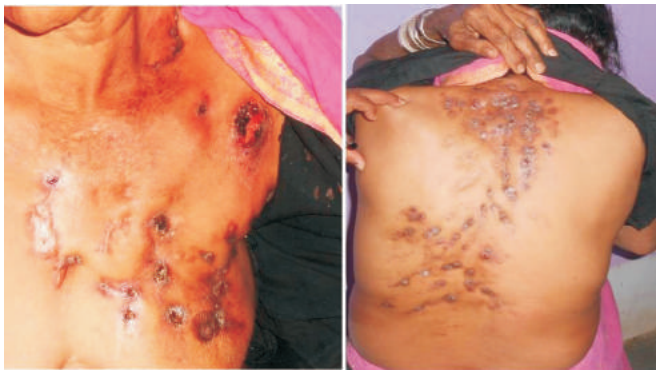
Due to their frequent occurrence as laboratory contaminants, it must be demonstrated by isolation in culture plus histologic evidence of its presence in tissues [9]. In our patient, the pattern of tissue reaction was suggestive on biopsy of deep fungal infection but it failed to reveal the presence of fungal hyphae. This could be attributed to small size of the tissue sample due to unwillingness of the patient to permit a bigger incisional biopsy resulting in lesser tissue availability for the sampling in histopathology and microbiology. Also, occasionally a superficial biopsy from the lesion may miss the underlying foci of activity. Hence, multiple deep biopsies or preferably a deep incisional biopsy should be advocated to avoid this diagnostic pitfall as in our case. Since biopsy may not be conclusive at all times due to the above mentioned pitfall, a simple bed side test like microscopic examination by KOH at times acts as an important aid in giving important clue to diagnosis and further management.

Therapy is not standardized given the lack of comparative clinical trials, because these are rare infections. Many antifungals have been used with variable success. Triazoles such as voriconazole, posaconazole, and itraconazole are the most active antifungal agents available [1]. Itraconazole is the preferred drug of choice, because of the lower toxicity and easier administration, and because there is greater clinical experience [11], Surgical excision may be effective, but in our case was not feasible due to extension of the lesions.

Legends

Figure.1- Multiple skin coloured to erythematous firm

tender crusted nodules with bridging scars over left supraclavicular area, mammary area and back



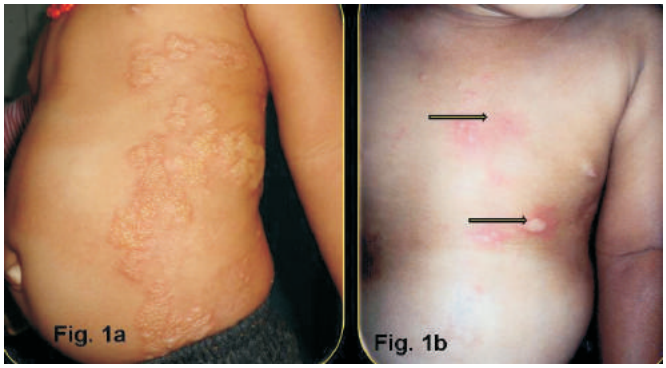
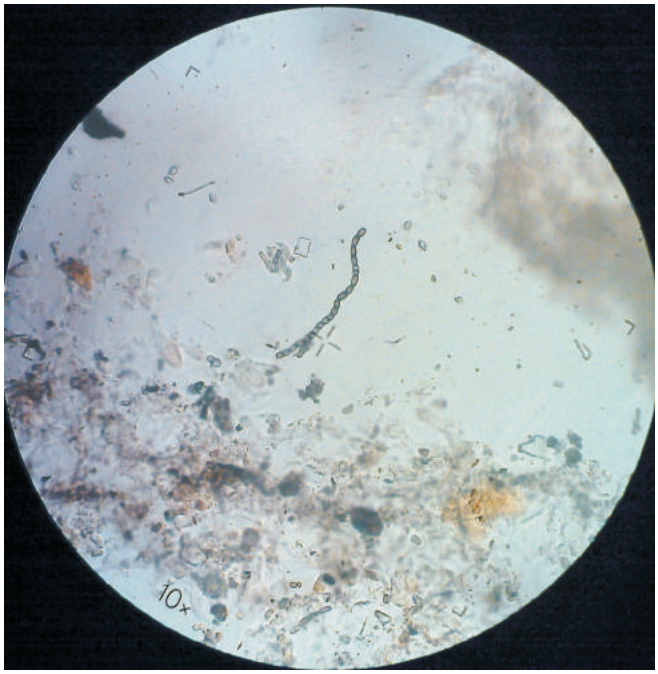


Figure.2- Broad septate brown pigmented fungal hyphae on KOH mount



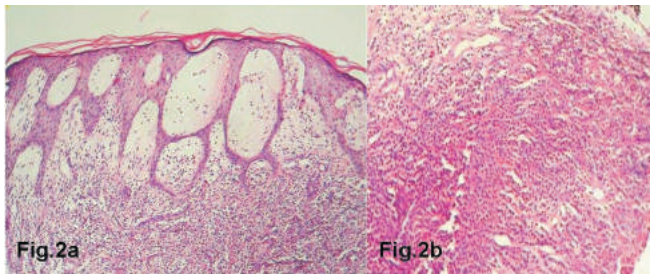
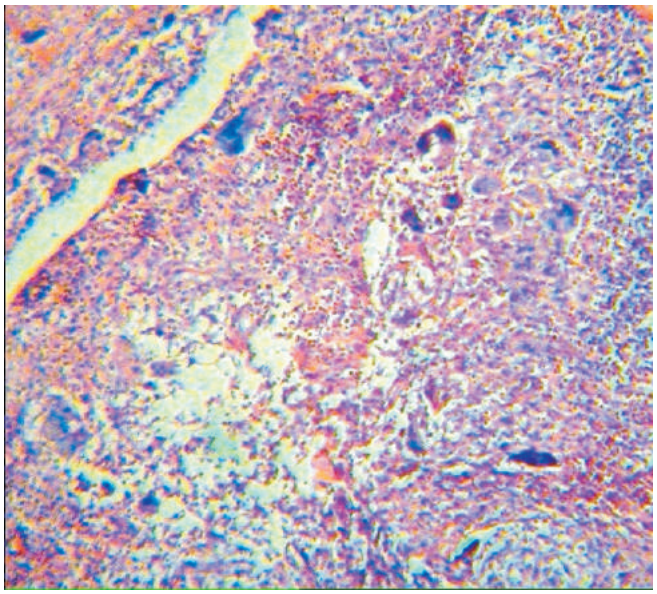


Figure.3- Suppurative granulomatous infiltrate consisting admixture of neutrophils, lymphocytes, plasma cells, epithelioid cells and foreign body giant cell involving the mid and lower reticular dermis on hematoxylin and eosin stain at 10x magnification



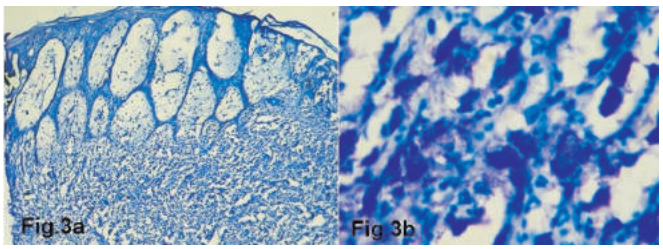
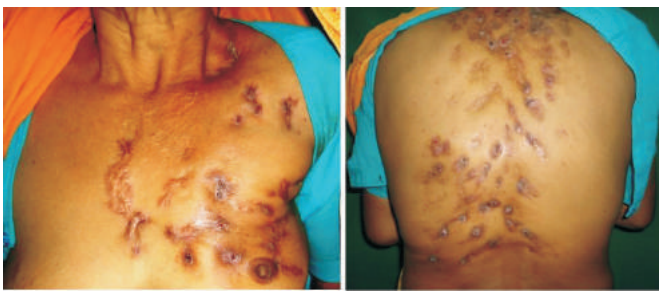


Figure.4- Post treatment pictures after 4 months of itraconazole



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