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# PREFACE TO THE 2<sup>nd</sup> ISSUE OF 8<sup>th</sup> VOLUME OF NATIONAL JOURNAL OF MEDICAL AND ALLIED SCIENCES 2019

## **Prof. Syed Esam Mahmood**

## **Chief Editor**

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In this issue, twelve original research articles are published. In the first article, Kumar et al. conducted a study which focused on inspecting logistics availability, vaccination actual techniques, and safety issues at routine immunization session sites of primary health centers of Etawah district. Ninety immunization sessions were conducted. There was lack of supervision and provision of health education through IEC material observed. There was also lack of waste disposal measures. It has been recommended that activities like orientation training of ANM for waste management should be planned and repeated further at regular intervals.

In the second article, Rai et al. conducted a prospective study which included 52 patients with chronic wounds of varying aetiology, admitted to the indoor patient care unit of general surgery department of Era's Lucknow Medical College, Lucknow. The efficacy of negative pressure dressing in wound healing was assessed. Negative Pressure Wound Therapy (NPWT) was found to be a useful choice for treatment of wounds when compared to other treatments in terms of reduction in wound size.

In the third article, Saxena et al. have attempted to make an immediate diagnosis of acute abdomen cases, with the help of different imaging techniques, so as to minimize mortality and morbidity. Maximum number of patients was of intestinal perforation followed by acute appendicitis, acute cholecystitis, and acute intestinal obstruction, torsion of ovarian cyst, renal or ureteric calculi and acute pancreatitis. Out of total seventy five study subjects, 63 cases were managed by surgery and rest by conservative treatment. The role of CT scan in acute appendicitis and acute pancreatitis was superb. However, in cholecystitis and renal stones USG remained as the primary imaging technique.

In the fourth article, Singh et al. have determined the oral health status of patients attending a tertiary care hospital in District Lucknow. One fourth study subjects were found to have periodontal disease. Approximately three fourth were suffering from bad breath, tooth decay, oral cancer, mouth sores, tooth erosion, tooth sensitivity and toothaches. The authors concluded that strengthening of dental health education is required to improve oral health standards among Indian population.

In the fifth article, Rai et al. have compared the efficacy of negative pressure wound therapy and saline moist gauze dressing in patients admitted with open wounds in a tertiary hospital of Northern India. The authors concluded that NPWT can be considered as a better option in the management of open wounds.

In the sixth article, Goel et al conducted a community based study in five select villages of Panipat involving 292 live births. The study reports that economic. educational occupational status of mother and her anthropometric values have effect on birth weight of babies. Therefore, health and nutrition education to mothers is need of the hour.

In the seventh article, Deo et al examined the impact in the timing of Continuous Renal Replacement Therapies (CRRT) application on outcome of sepsis patients with Acute Kidney injury (AKI). It was observed that the sepsis patients with AKI with higher SOFA who underwent CRRT showed better results than patients with lower SOFA score. It was concluded that biomarkers could be helpful to define AKI but also to recognize damage to the kidney in an early stage and to evaluate preventive strategies.

In the eight article, Mishra et al conducted a study to evaluate hepatic vein waveforms and serum lipid profile in patients with cirrhosis and to study prognostic value of hepatic vein waveform and lipid profile as single parameters in patients with cirrhosis in Lokmanya Tilak Municipal Medical College, Sion. The authors concluded that right hepatic vein waveform showed definite alterations with development of cirrhosis. Flat waveform in right hepatic vein was found to be a significant prognostic marker in patients with cirrhosis.

In the ninth article, Pandey et al conducted a cross-sectional survey to assess the mean micronutrients levels in children of nutritional anaemia having Iron, Folate, and Vitamin B12 deficiency. Mean iron level was found to be significantly low in females, children living in rural areas, of low socioeconomic status and those malnourished/underweight. It was concluded that more intensified programmes are needed especially for female children, children of rural areas, low socioeconomic status and malnutrition/underweight.

Surgical site infections (SSI) comprise a foremost public health problem worldwide. They are responsible for increasing the treatment cost, length of hospital stay and significant morbidity and mortality. In the tenth article, Thokar et al undertook a study to ascertain the bacterial etiology of SSI in humans and to determine antibiotic susceptibility pattern of the isolates. Gram positive organisms were found to be the major cause of SSI. Organisms were resistant to commonly used antimicrobial agents, Penicillin, Ciprofloxacin, Levofloxacin, Tetracycline. It was concluded that appropriate use of antibiotics and proper aseptic practices can reduce the rate of SSL

Gall bladder diseases are common clinical entity affecting the adult population, presentation may range from flatulent dyspepsia, acute cholecystitis and its complications like gangrene, perforation, peritonitis, empyema, chronic cholecystitis and carcinoma of gall bladder. In the eleventh article, Katiar et al observed the epidemiological trends and the clinical aspects of gall stones diseases and cancer of gall bladder in Kanpur District. Out of 77 gall bladder disease cases, three fourth were benign and one fifth was malignant. The study concludes that early detection and treatment of such cases is required.

Breast cancer is the most common cancer in reported worldwide with approximately one million new cases each year as well as one of second leading cause of death among females. In the twelfth article, Kumar et al conducted a study to find the causes and associated factors of breast lumps in females who attended the surgical clinic of a tertiary hospital of District Kanpur. Mean age of the patients was found to be 49.66 years. Early age of menarche had predisposition towards breast cancer. It was concluded that early detection and effective management of the disease is the need of the hour.

As 2019 draws to a close, I am delighted to report to our readers that the Index Copernicus Value (ICV) for 2018 has been released. The ICV is 85.77. The Cosmos Impact factor for 2018 has also been calculated. It is 4.465.

I would like to thank all the reviewers, authors and my team members for their excellent work and constant support. I look forward to a new and exciting year in 2020. Let me wish all our readers a Happy New Year.

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## ASSESSMENT OF ROUTINE IMMUNIZATION IN RURAL AREAS OF ETAWAH OF THE DISTRICT OF UTTAR PRADESH

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## **ABSTRACT**

**Introduction:** Vaccine-preventable infectious diseases are one of the main causes of morbidity and mortality in children that can easily be prevented by immunization. Vaccination is proven and one of the most cost-effective child survival interventions. All countries in the world have an immunization program to deliver selected vaccines to the targeted beneficiaries, especially focusing on pregnant women, infants, and children who are at a high risk of diseases preventable by vaccines.

**Materials and Methods:** The present cross-sectional study was conducted in rural areas of Etawah district in January 2018- August 2018. Total 90 immunization sessions were conducted. Information was gathered with the help of a pre-tested structured questionnaire.

**Results:** Supervision by the higher authority was only in 17.3% of session sites. Information, education, and communication (IEC) material was displayed only in 27.7% of session sites. Four key messages by auxiliary nurse midwife (ANM) were given in only 40.0% of session sites. Due list was available in 64.4% of session sites. About 23% session sites had no mobilizers. Vaccine and diluents were available in 77.8% of session sites. 88.4% sessions were conducted as per plan.

**Conclusion:** There was a lack of supervision and provision of health education through IEC material. There was also a lack of waste disposal measure. Activities like orientation training of ANM for waste management should be planned and repeated at regular intervals.

**Keywords:** Process evaluation, special immunization, session sites, vaccines, and logistics

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## INTRODUCTION

Vaccines are a cost-effective method of preventing many infectious diseases. Several deaths in premature children can be prevented by immunization. Vaccine-preventable infectious diseases are one of the main causes of morbidity and mortality in children that can easily prevent by immunization.<sup>2</sup> Immunization has been one of the most significant, cost-effective and stimulatory public health interventions. About one-quarter, or 25%, of under-5 mortality, is due to vaccine-preventable diseases.<sup>3</sup> All countries in the world have an immunization program to deliver selected vaccines to the targeted beneficiaries, especially focusing on pregnant women, infants, and children who are at a high risk of diseases preventable by vaccines.<sup>4</sup> The quality of vaccines is one of important factor for the success of immunization programme which in turn depends on proper storage and handling of vaccines.<sup>5</sup> In spite of lots of effort by government and other health agencies, approximately 10 million children and infants in India remain unimmunized which is the highest number of such children in the world. <sup>6</sup> In 1974, WHO launched Expanded Programme on Immunization (EPI) against six most common preventable childhood diseases. The Government of India launched EPI in 1978 with the objective of reducing mortality and morbidity from vaccinepreventable diseases of childhood.<sup>7</sup> It was realized that merely providing vaccine just to achieve targets without giving adequate attention to the quality of services immunization doesn't guarantee a reduction in disease morbidity & mortality.8

This study was undertaken to focus on inspecting actual logistics availability, vaccination techniques, and safety issues at Routine Immunization (RI) session sites of Primary Health Centres (PHC) of Etawah District.

## MATERIAL AND METHODS

The present cross-sectional study was conducted in rural areas of Etawah district in Jan 2018-Aug 2018 after obtaining Ethical committee permission from ethical committee of UPUMS, Saifai.

Ninety immunization session sites were monitored during routine immunization. 90 sites were randomly selected from 27 PHCs of 8 blocks of Etawah district. At each session site auxiliary, nurse midwife/female health worker (ANM/FHW) was interviewed by pretested and predesigned performa and monitored for the vaccine administration and logistic. Data was entered and analyzed using Microsoft Excel 2010. Results were presented in the form of percentages.

## **RESULTS**

Table 1 shows that out of 90 session sites that were monitored the list of beneficiaries was available in 64.4% sessions and mobilizers were present in 76.6% sites. ANM gave four key messages only in 40.0% sessions and Information, Education, and Communication (IEC) material was displayed only in 27.7% session sites.

Table 2 shows that the status of the vaccine administration process evaluation during immunization was found to be satisfactory. Of 90 session sites, ANM administrated the vaccines using the correct technique in 94.5%. Correct site and route of vaccination were found in 100%, an adequate dose of vaccine was found in 100% and correct age of administration was found in 95.5% session sites.

Table 3 shows status of cold chain, logistics, safety issues at session. It was found that all vaccines along with diluents were available in 77.8%, auto-disable syringes and needle were available at 95.0% and time of reconstitution was written on vial at 91.1% session sites. ANM was using hub cutter and disposed waste in proper manner only at 53.3% session sites. During monitoring, no stick injury to ANM was found.

Table 1: Status of IEC activity and infant mobilization during an immunization session

Parameters	Number N=90	Percentage
Due list of beneficiaries available	55	64.4
Mobilizer present	69	76.6
All four key messages after vaccination given by ANM	36	40.0
IEC material displayed	25	27.7

IEC: Information education communication, ANM: Auxiliary Nurse Midwife

Table 2: Status of vaccine administration process evaluation during immunization session

Parameters	Number N=90	Percentage
Correct administration technique	85	94.5
Correct site and route of administration	90	100
Correct dose of vaccine	90	100
Correct age of administration	86	95.5

Table 3: Status of cold chain, logistics, and safety issues at session site

Parameters	Number N=90	Percentage
All vaccines along with diluents available	70	77.8
AD syringes and needle available	85	95
Time of reconstitution written on the vial	82	91.1
Using hub cutter and proper disposal of waste	48	53.3
Needles prick injury to ANM	0	0

ANM: Auxiliary nurse midwife, AD: Auto disabled

## **DISCUSSION**

For achieving high coverage of immunization and better function of the system supervision is an essential factor. Supervision by the higher authority was only in 17.3% of session site that was much lower may be due to lack of planning of supervision. IEC materials were displayed only in 27.7%, which also was poor as during vaccination we can provide information about the vaccine and important health-related issue to the attendant by IEC. Four key messages are essential for the success of immunization and must be given to the attendant of the beneficiary because without these messages attendant does not know where to come for next visit, what are the possible side effects. In the present study, we found that four key messages by ANM were giving in only 40.0% of the visited site that was unsatisfactory. In 48% of the session, hub cutter was used and the proper disposal of waste was done so there was bio waste problem.

List of the beneficiary was available in 64.4% of session site. The infant mobilization to session site reduces if we are not preparing the list of due beneficiary infants. Manjunath and Pareek in his study reported that around 9.7% of mothers lacked information about the session as on maternal knowledge perception and about routine immunization.<sup>9</sup> These mothers require active mobilization. Only one or two mobilizers were present in session at 76.6% sessions and at 24.4% there were no mobilizers. Parmar et al had also found 100% presence of AWW, ASHA, and FHW at all session sites. At 92% of sites, community mobilization was done by ASHA and AWW.10 Regarding the availability of vaccine and diluents were available in 77.7% of the site. This was mainly because of the shortage of bacillus Calmette Guérin (BCG) vaccine and non-availability of a colored bag for waste disposal. In National Immunization Program review no tracking of dropouts and left outs and missing opportunities due to wastage concerns were also identified.<sup>11</sup> In cold chain and logistics at vaccine sites, vaccine vial monitor for polio and pentavalent vaccine and shake test for freeze sensitive vaccine were satisfactory. However, reconstitution time was not written on vaccine vial for almost 8.9% of the site, which is important for the prevention of toxic shock syndrome that may occur in the measles vaccine. Other vaccine safety aspects like the correct site for vaccination, dose, and age were satisfactory. The injection safety issue was also good in the district. No ANM reported needle prick injury that is because of proper training on vaccine administration. Pandit and Choudhary in his study from the same district in 2004. 12 He has reported more than 19% of annual needle stick injuries among service providers in district Anand, India. 81.6% of sessions were conducted as per plan. About 18.4% of sessions were not conducted as per micro-plan due to various reasons such as session planned in routine immunization, the session will be planned a few days back, staff deputed for training, staff on leave, and vacant post. Lack of staff and resources for service delivery has also been reported by the National Immunization Program review by WHO.<sup>12</sup>

## **CONCLUSION**

In the present study, there was a lack of supervision and there was a lack of providing health education through IEC material. There was a lack of waste disposal measure. There was a lack of mobilization of beneficiaries. The planning process and maintaining a cold chain process were good. All logistics were available except for the shortage of BCG vaccine. The cold chain was properly maintained. Vaccine administration process was good.

#### RECOMMENDATION

Activities like orientation training of ANM training for waste management should be planned and should be repeated at regular interval. Strengthening the cold chain systems should be done. Vacant posts of FHWs should be filled so that all sessions can be conducted. IEC material should be displayed which provide the opportunity of giving health education to the parents of the beneficiary.

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# EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY IN OPEN WOUNDS: A PROSPECTIVE STUDY

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#### **ABSTRACT**

**Introduction:** Acute and chronic open wounds affect at least 1% of the population. These wounds may heal or may result in hospitalization, amputation, sepsis and even death. One of the most significant discoveries in wound management is the improvement of wounds with negative pressure wound therapy (NPWT). In this study, the efficacy of negative pressure dressing was assessed in wound healing.

**Materials and Methods:** Fifty-two patients were included in the study who admitted in indoor patient care unit of Department of General Surgery of the Era's Lucknow Medical College, Lucknow during the period October 2014 to April 2016 fulfilling all the inclusion criteria. Data entry and descriptive analysis were performed using the Microsoft Excel.

**Results:** Mean age of patients was 38.32±12.32 years. Majority of patients were within 40 years of age (58.7%). Majority were males (71.15%). Hundred percentage wounds presented with dead/devitalized tissue. Culture positivity and pus discharge were seen in 98.08% and 90.38% cases respectively. Random blood sugar showed maximum variation in the observed values among rest of the Hematological/Biochemical Variables. Recurrence/persistence of infection rate was 44.23%, % Reduction in wound size and wound depth was 45.92±5.42 and 56.82±21.62 respectively.

**Conclusion:** NPWT therapy is a useful choice for treatment of wounds when compared to other treatments in terms of reduction in wound size.

**Keywords:** Negative pressure, wound therapy, wound size, indoor patient

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## INTRODUCTION

Wound dressings developed very slight for many years until 1867, when Lister introduced antiseptic dressings by soaking lint and gauze in carbolic acid. Meanwhile then, numerous more sophisticated products have become available. Wound healing is most successful in moist, clean and warm atmosphere. Studies have demonstrated that the rate of epithelialization under a moist occlusive dressing is twice that of a wound that is left uncovered and allowed to dry. An occlusive dressing provides a mildly acidic pH and low oxygen tension on the wound surface which is conducive for fibroblast proliferation and formation of granulation tissue.

However, wounds that produce significant amounts of exudate or have high bacterial counts require a dressing that is absorptive and prevents maceration of the surrounding skin. These dressings also need to reduce the bacterial load while absorbing the exudate produced. One of the most significant discoveries in wound management in recent decades is the improvement in wounds with negative pressure wound therapy. This modality has many uses and has found its way into the armamentarium of a wide array of surgical and nonsurgical specialties. It should best be thought as an adjunct to assist in surgical closure of a problem wound. Earlier the most common modality of treatment was

conventional wound dressing. But recent studies have shown that application of a sub atmospheric pressure in controlled manner to the wound site has got an important role in assisting wound healing. Negative pressure wound dressing is a new technology that has been shown to accelerate granulation tissue growth and promote faster healing, thereby decreasing the period between debridement and definite surgical closure in large wounds. Vacuum-assisted wound closure (VAC) is a wound management technique that exposes wound bed to negative pressure and provides a moist wound-healing environment. This technique has been developed and popularized world-wide by Prof. Louis Argenta <sup>2</sup> and Prof. Micheal Moryk was <sup>4</sup> from the USA and by Dr Win Flies chmann from Germany.<sup>5</sup> Wound and their management are fundamental to the practice of surgery. Dressings are applications for wounds to provide the ideal environment for wound healing. Many studies have conducted comparing various dressing modalities for different types of wounds. <sup>6,7</sup> In this study, the efficacy of negative pressure dressing was assessed in wound healing.

## **MATERIAL AND METHODS**

This prospective study included 52 patients with chronic wounds of varying aetiology, admitted to the indoor patient care unit of Department of General Surgery of Era's Lucknow Medical College, Lucknow, from October 2014 to April 2016 satisfying all the inclusion criteria mentioned below after the clearance from the ethical committee was obtained. The main inclusion criteria were (a) Patients with acute large wounds (≥ 5 cm in shortest length) (b) Patients with chronic, non-healing wounds ( $\geq 1$  month duration,  $\geq 3$  cm in shortest length) and (c) Patients giving consent for topical negative pressure dressings. The main exclusion criteria for the study included (a) Patients with untreated osteomyelitis, Non-enteric and unexplored fistulas, Malignancy in the wound, Exposed vasculature, Exposed nerves, Exposed anastigmatic site, exposed organs (b) Age less than 15 years and more than 75 years. (c) HCV/HBsAg positive patients (d) Multiple wounds (e) Patients receiving Chemotherapy or Radiotherapy Moribund patient (g) Patient who changed management due to non-medical reasons, patients not completing the prescribed treatment.

A predesigned form was used to record the data. Careful history was taken to determine any etiological factors and history of steroid intake or others factors for non-healing wounds. Examination of the wounds was for size (area in centimetre square), depth (in millimetre), presence or absence of dead/devitalized tissue and foreign body; signs of infection and presence or absence of granulation tissue were taken. Also, data was collected by recording details of the onset of the wound, progress of the wound and its characteristics with respect to appearance of granulation tissue and percentage of increase along with demographic details.

## **Statistical analysis**

Data entry and descriptive analysis were performed using the Microsoft Excel. The values were represented in number, percentage, mean and standard deviation.

## **RESULTS**

The present study was conducted in the Department of Surgery, Era's Lucknow Medical College & Hospital, and Lucknow to evaluate the efficacy of "Negative Pressure Wound Therapy". A total of 52 patients aged 19-75 years with chronic, non-healing wounds ( $\geq 1$ -month duration,  $\geq 3$  cm in shortest length) or with acute large wounds ( $\geq 5$  cm in shortest length) were included in the study.

Table 1: Distribution of respondents according to their demographic characteristics

Variables	Frequency		
	No.	%	
Age Group			
Upto 20	0	0.00	
21-30	22	42.31	
31-40	10	19.23	
41-50	11	21.15	
51-60	4	7.69	
61-70	5	9.62	
Mean±SD	38.40	)±12.64	
Gender			
Female	15	28.85	
Male	37	71.15	
Male: Female	1:0.41		

Table 1 depicts that the distribution age – gender od the study subjects. In which, Age of patients ranged between 19 and 69 and mean age was 38.32+12.32 years Majority of subjects were belongs to age

group 21-30 years. Admission of subjects were decreases as the age group increases .Out of 52 patients, only 15 (28.85%) were females and 37 (71.15%) males. Male: Female ratio was 1:0.41

Table 2: Distribution of respondents according to their Condition of Wound

Variables	Frequency		
	No.	%	
Exposed Bone	27	51.92	
Dead/ Devitalized tissue	52	100.00	
Pus Discharge	47	90.38	
Granulation	0	0.00	
Culture positive	51	98.08	

Table 2 illustrates that the distribution of respondents according to their Condition of Wound. Proportion of patients with Dead/ Devitalized tissue was higher as compared to other categories. In all the patients, granulation was found in none of the patients. In all the patients, mode of intervention was debridement. Fifty-one patients showed culture positive. Followed by condition of wound Pus Discharge i.e., (90.38%)

Table 3: Distribution of respondents according to their Haematological/Biochemical Variables

Variables	Mean	SD
Hb (g/dl)	11.12	1.74
RBS (mg/dl)	154.85	51.54
FBS (mg/dl)	167.17	33.68
BS_PP (mg/dl)	257.10	49.29
HbA1c (%)	8.07	0.71
Total protein (g/dl)	7.24	0.56
Serum albumin (g/dl)	3.66	0.29

Table 3 shows that the mean and standard deviation of Haematological/Biochemical Variables of respondents. Mean value of BS\_PP (mg/dl) was highest among rest of the Haematological/Biochemical Variables. Followed by FBS (167.17mg/dl). Average haemoglobin level of respondents was 11.12 g/dl. Mean percentage of HbA1c was 8.07%. Serum albumin (g/dl) showed minimum mean value i.e., (3.66g/dl) . RBS (mg/dl) showed maximum variation in the observed values.

**Table 4: Distribution of respondents according to Recurrence** 

Variables	Frequ	uency
	No.	%
No recurrence, persistent,	29	55.77
infection		
Recurrence/ Persistent/ Infection	23	44.23

Table 4 shows that the percentage distribution of respondents according to Recurrence. In which,

observed that majority of the study subjects hadn't recurrence, infection or persistence of wound, which was found 29 (55.77%). Proportion of patients with no recurrence was higher as compared to Recurrence/ Persistent/ Infection. 44.23% of study subjects had Recurrence/ Persistent/ Infection.

Table 5: Distribution of respondents according to their Size & Depth of wound and Reduction after treatment

Variable s	Before Treatment		After treatment		Redu aft treat	ction er
	Mean	SD	Mea	SD	Mea	SD
			n		n	
Size of	170.4	107.5	91.50	58.1	45.92	5.42
wound	6	2		0		
Depth of	13.37	6.05	6.13	4.02	56.86	21.6
wound						2

Above table depicts that the distribution of respondents according to their Size & Depth of wound and percentage of Reduction after treatment. Observed that before treatment size of wound of study subjects was (170.46+107.52 cm²). After treatment mean size of wound was (91.50+58.10 cm²). Mean reduction in size of wound (decline) was 45.92+5.42%. Whereas, wound depth before treatment among study subjects was (13.37+6.05 mm). Wound depth after treatment among study subjects was (6.13+4.02 mm). Mean reduction in wound depth was 56.86+21.62%.

## **DISCUSSION**

Negative pressure wound therapy (NPWT) has played a major role as a bridge to reconstruction. It is a significant, clinically proven advancement in wound care that promotes active wound healing at the cellular level through negative pressure. 4,8 systematic reviews have confirmed its consistency and benefits for some specific types of wounds. 9 However, there is still debate whether NPWT provides benefits in all types of wounds. 10 In India, some of the clinical trials evaluating role of NPWT in various types of wounds have shown a promising response. 11-14 Considering these positive responses for NPWT in these studies, the present study was carried out with an aim to assess the efficacy of negative pressure wound therapy. Finally, age of patients ranged from 19 to 69 years with a mean age of 38.32±12.32 years. Majority of patients were within 40 years of age (58.7%). Wounds are not age-barred, they can occur in any age. Most of the studies on treatment of wounds have included patients with diversified age groups. McCallon et al. (2000) <sup>15</sup> in their study included patients aged 18 to 75 years whereas in the study of Moisidis et al. (2004) <sup>16</sup> in their study included patients aged 27 to 88 years. But researchers like Svensson et al. 17 had an extraordinarily high age of patients in their study with median age 75 years. As a matter of fact, age has a definitive impact on wound healing. 18-21 In present study, majority of patients were males (71.15%). Male to female ratio was 1:041. As such, there is no systematic study available evaluating the effect of gender on wound occurrence in general, however, some epidemiological studies on chronic wounds indicate a higher crude prevalence rate among women as compared to men. 22 appearance all the patients' wounds presented with dead/devitalized tissue (100%). Culture positivity and pus discharge were seen in 98.08% and 90.38% cases respectively. In present study, mean value of BS PP (mg/dl) was highest among rest of the Haematological/Biochemical Variables. Mean percentage of HbA1c was 8.07%. Serum albumin (g/dl) showed minimum mean value i.e., (3.66g/dl). RBS (mg/dl) showed maximum variation in the observed values. In addition, Glycaemic control, hemodynamic, serum protein levels, systemic status have been suggested to play a role in wound healing. 18,23,24 In present study, recurrence/persistent infection was seen in 44.23% of NPWT. NPWT has been reported to have a superior infection control as compared to conservative management of wounds. Stannard et al. 25 in their study showed infection rate to be half in NPWT group as compared to pressure dressing group. In a study from India, Siddha et al. <sup>14</sup> also showed infection clearance rate to be almost double in NPWT as compared to conventional betadine dressing. In present study, in terms of percentage reduction in wound size it was 45.92±5.42% in NPWT group. NPWT has shown a greater wound size reduction as compared to other treatment modalities in different studies. 26,27 Mouës et al. <sup>28</sup> in another study reported mean reduction in sound surface area to be 3.8%/day for NPWT as compared to 1.7%/day for conventional-treated wounds. Thus, present study showed that the

NPWT dressing can be considered as a superior option in the management of chronic wounds Furthermore, Page et al. <sup>29</sup> conducted a retrospective analysis of negative pressure wound therapy in open foot wounds with significant soft tissue defect and concluded that negative pressure wound therapy reduced the risk of complications, subsequent foot surgeries and hospital readmissions by 70% or more. In a study conducted by Weed et al <sup>30</sup> concluded that NPWT has become an accepted treatment modality for acute and chronic wounds.

## **CONCLUSION**

On the basis of findings of present study, it can be concluded that negative pressure wound therapy is a useful choice for treatment of wounds when compared to other treatments in terms of reduction in wound size. Further studies on a larger number of sample size including both chronic and acute wounds are recommended to evaluate the treatment response under variable wound types.

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# A CROSS SECTIONAL STUDY ON ORAL HEALTH STATUS OF PATIENTS ATTENDING A TERTIARY CARE HOSPITAL

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#### **ABSTRACT**

**Introduction:** WHO recently published a global review of oral health which emphasized that despite great improvements in the oral health of populations in several countries, global problems still persist. This is particularly so among underprivileged groups in both developing and developed countries. The objective of this study was to determine the oral health status of patients attending a tertiary care hospital in District Lucknow.

**Material and Methods:** This hospital based and cross-sectional design study was carried out in patients attending the outpatient department of Department of Dentistry, Integral Institute of Medical Sciences & Research, Lucknow over a period of six months from February 2019- July 2019. The study was approved by the Institutional Research Committee. Data entry and management were carried out using MS excel spreadsheet. Result was analyzed by calculating descriptive statistics.

**Results:** One fourth study subjects had periodontal disease. Approximately three fourth of the study subjects were suffering with other problems such as bad breath, tooth decay oral cancer, mouth sores, tooth erosion, tooth sensitivity and toothaches. Majority of subjects belonged to age group 12 years and above. Only 5.26% subjects with periodontal disease belonged to less than 6 years of age.

**Conclusions:** Comprehensive preventive programs for oral health care are still lacking, and more dental health education is needed to improve oral health standards among Indian population.

Keywords: Periodontal Disease, incidence, oral health

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## INTRODUCTION

Individuals with special health care needs have been reported in literature to have poorer oral hygiene and periodontal status, more untreated caries and fewer remaining teeth. <sup>1-3</sup> They are those who have physical, mental, sensory, behavioral, cognitive, emotional and chronic medical conditions which require health care away from that considered routine, which involves and specialized information, increased awareness, attention and accommodation.<sup>4</sup> Their oral health situation may be influenced by age, severity of destruction and living conditions. Individuals with special needs may have great restrictions in oral hygiene performance due to their likely motor, sensory and intellectual disabilities. <sup>5-7</sup> and so are prone to poor oral health. This group of individuals may also not appreciate and assume accountability for or cooperate with preventive oral health practices. <sup>8</sup> Those who are very young, those with severe impairments, and those living in institutions are dependent on parents, siblings or caregivers for general care including oral hygiene. Many care givers do not have the necessary knowledge or values to recognize the significance of oral hygiene and do not themselves practice appropriate oral hygiene or choose a proper diet. <sup>9</sup> They may be more vulnerable to dental caries if they reside at home and are pampered with cariogenic snacks and other unhealthy eating habits. Studies on select populations show that children

with special health care needs have both additional dental problems and more untreated dental disease relative to other children. <sup>10,11</sup> Poor oral health conditions have also been linked to low socioeconomic status. Poor and nearly poor children with unusual health care needs and those with greater restrictions attributable to disability were more likely to have unmet dental care needs. <sup>12</sup> Previous studies on this group of individuals in our environment show that they had high unmet needs, especially periodontal treatment needs. <sup>13-15</sup> This study was carried out to determine the oral health status of patients attending a tertiary care hospital in District Lucknow.

## MATERIAL AND METHODS

This cross-sectional study was done in the department of Dentistry, Integral Institute of Medical Sciences and Research, Lucknow. The study was carried out in 3743 study subjects attending the outpatient department over a period of six months from February 2019- July 2019.

## **Data Collection**

Simple random sampling technique was used for selecting study subjects. After establishing the rapport with the respondents, the schedule was administered in Hindi after taking their consent.

A pre-designed pre-tested structured questionnaire was administered to the subjects through personal interview by the researcher. The respondents were interviewed personally by the investigator to get first-hand information as well as the real picture of their oral health status through direct observation.

All subjects were explained about the study. Medical terms used in the questionnaire related to causes, signs, and symptoms of periodontal diseases were also explained. Once completed, each questionnaire was double-checked to make sure that all the items were answered and study subjects were requested to complete any missing data. The data were processed by the computer after auditing, reviewing, and coding the completed questionnaires for data processing and analysis.

## **Ethical consideration**

The study was approved by the Institutional Research Committee & the Institutional Ethics Committee.

## **Statistical Analysis**

Data entry and management were carried out using MS excel spreadsheet and software. A result was analyzed by calculating descriptive statistics. Data were presented in number and percentage.

## **RESULTS**

The study comprised of 3743 study subjects attending the Outpatient department of Dentistry, Integral Institute of Medical Sciences and Research, Lucknow.

Table 1: Incidence of periodontal and other dental diseases according to gender

Disease	N.	<b>I</b> ale	Fe	male
	No. %		No.	%
Periodontal	429 23.74		481	24.85
Others	1378	76.26	1455	75.15
Total	1807	100.00	1936	100.00

Table 1 illustrates that the frequency distribution of study subjects with respect to periodontal and other dental diseases. Out of total of 3743 study subjects, 1936 were females and 1807 were males. In females, 24.85% were having periodontal disease and rest had other diseases. On the other hand, 23.74% males were suffering with periodontal disease. Percentage of periodontal disease was high among females as compared to males.

Table 2: Incidence of periodontal and other dental diseases according to age

Disease	< 6 years		6 - <12 years		6 years 6 - <12 year		≥12	years
	No.	%	No.	%	No.	%		
Periodontal	2	5.26	8	4.76	900	25.45		
Others	36	94.74	160	95.24	2637	74.55		
Total	38	100.00	168	100.00	3537	100.00		

Table 2 shows the age wise distribution of incidence of periodontal and other dental diseases. Majority of study subjects were belonging to age group equal to or above 12 years. In this group 25.48% of study subjects had periodontal disease. In age group 6 to less than 12 years, only 4.76% had periodontal disease. Only 5.26% study subjects who belonged to less than 6 years had periodontal disease. (Table 2)

Table 3: Month wise distribution of incidence of periodontal disease

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Months	Incidence (No.)	%
February	160	17.58
March	207	22.75
April	170	18.68
May	110	12.09
June	92	10.11
July	171	18.79
Total	910	100.00

Table 3 shows monthly distribution of incidence of periodontal diseases, Incidence was highest in the month of March i.e., 22.75%. Followed by July i.e., 18.79%. Incidence of periodontal diseases in April and February were 18.68% and 17.58% respectively. June showed the minimum percentage of incidence (10.11%). In the month of May there was 12.09% of incidence of periodontal disease. From the above table, we observed that there were monthly variations in the incidence of periodontal diseases. (table 3)

Table 4: Overall distribution of Incidence of periodontal and other dental diseases

Disease	Incidence (No.)	%
Periodontal	910	24.31
Others	2833	75.69
Total	3743	100.00

Out of total 3743 study subjects, approximately one fourth study subjects had periodontal disease. Approximately three fourth of the study subjects were suffering with other diseases such as bad breath, tooth decay, oral cancer, mouth sores, tooth erosion, tooth sensitivity and toothaches. (table 4)

## **DISCUSSION**

The aim of this study was to compare the oral health status of patients attending a tertiary care hospital in District Lucknow. The main cause of periodontal disease is bacterial plaque although many other factors such as hormonal changes, diabetes, poor nutrition, smoking, and stress may affect the initiation and progression of gingival and periodontal diseases. The development of the common periodontal diseases depends mainly on

human behaviour, and the control of these diseases is greatly supported by the fact that the etiological factors are well documented. 17 Lack of both parents and children oral health education might also explain the findings of this study. Poor oral health knowledge among the participants in this study coincided with findings from the previous studies that reported lack of acceptable levels of knowledge and awareness of periodontal problems among adults. 18,19 Percentage of periodontal disease was high in females as compared to male study subjects in this study. In contrast to present study, Aggnur et al reported that majority of the subjects were males (82.1%) suffering with oral and dental health problem.<sup>20</sup> In the present study, majority of subjects belonged to age group 12 years or above. In this group 25.48% of study subjects had periodontal disease. Only 5.26% study subjects who had periodontal disease were aged less than 6 years. In the National Oral Health Survey aided by Dental Council of India, New Delhi. three-stage sampling design was adopted to select 210 rural and 110 urban subjects in each of the age groups, viz. 5, 12, 15, 35-44, 65-74 years, from each homogeneous region comprising of a number of districts of each state. The prevalence reported was 57%, 67.7%, 89.6% and 79.9% in the age groups 12, 15, 35-44 and 65-74 years, respectively. <sup>21</sup> In addition, Taani showed that 25% of adults suffered bleeding gums on brushing and around the same percentage suffered bad breath. Nearly 40% of adults believed that they had periodontal disease. 18 WHO Global Oral Health Data Bank <sup>22</sup> indicates that symptoms of periodontal disease are highly prevalent among adults in all regions. Furthermore, most children and adolescents worldwide have signs of gingivitis. Aggressive periodontitis, a severe periodontal condition affecting individuals during puberty and which may lead to premature tooth loss, affects 2% of youth.<sup>23</sup> In present study, approximately one fourth study subjects had periodontal disease while approximately three fourth of the study subjects were suffering with other diseases such as bad breath, tooth decay oral cancer, mouth sores, tooth erosion, tooth sensitivity, toothaches. Furthermore, over the past years, savings in dental expenditures have been noted in industrialized countries which have invested in

preventive oral care and where positive trends have been observed in terms of reduction in the prevalence of oral disease. <sup>24,25</sup> In most developing countries, investment in oral health care is low. In these countries, resources are primarily allocated to emergency oral care and pain relief; if treatment were available, the costs of dental caries in children alone would exceed the total health care budget for children. <sup>26</sup>

## **CONCLUSION**

Globally, the maximum load of oral diseases is among the unfortunate and poor population groups. The current trend of oral disease reflects distinct risk profiles across countries related to living conditions, environmental factors and lifestyles, and the implementation of preventive oral health schemes. Comprehensive preventive programs for oral health care are still absent, and more dental health education is needed to improve oral health standards among Indian population.

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# COMPARATIVE STUDY OF EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY VERSUS CONVENTIONAL DRESSING IN OPEN WOUNDS

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#### **ABSTRACT**

**Introduction:** Several treatment methods have been utilized to improve wound healing process. These include various medical dressings, surgical debridement, topical applications and antiseptic medication. Negative pressure wound therapy is a relatively newer treatment modality. The aim of the present study is to compare the efficacy of negative pressure wound therapy (NPWT) and saline moist gauze dressing in patients admitted with open wounds.

**Materials and Methods:** This is a prospective comparative study conducted on 104 patients with open wounds of various aetiologies between October 2014 to April 2016. The patients were divided into two groups each group comprising of 52 patients. One group received negative pressure wound dressing while the other group received saline moist gauze dressing. Data entry and statistical analysis were performed using the Microsoft Excel. Values were represented in number, percentage, Mean  $\pm$  SD and Tests of significance were applied.

**Results:** Maximum number of patients had diabetic aetiology followed by necrotizing fasciitis/infective aetiology. Granulation tissue formation to be significantly earlier in NPWT group as compared to other group. Wound closure time was also achieved nearly 1.5 times faster in NPWT as compared to control group. Compared NPWT with saline wet-moist gauze and found this difference to be significant.

**Conclusions:** Negative pressure wound therapy can be considered as a better option in the management of open wounds.

**Keywords:** Negative pressure wound therapy, moist gauze, wound healing

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## INTRODUCTION

Chronic wounds, especially of the non-healing types, are one of the most common surgical conditions a surgeon comes across. Whatever the management given, chronic wounds, especially pressure ulcers or bed sores refuse to heal. The issue of chronic wound management still remains an enigmatic challenge. Empirically, the ancient physicians of Egypt, Greece, India and Europe developed gentle methods of treating wounds by removing foreign bodies, suturing, covering wounds with clean materials and protecting injured tissue from corrosive agents. <sup>1</sup> During the last two decades a wide variety of innovative dressings have been

introduced. Acute and chronic open wounds affect at least 1% of the population. These wounds may heal or may result in hospitalization, amputation, sepsis and even death. <sup>2</sup> Wound healing is a complex and dynamic process of replacing devitalized and missing cellular structures and tissue layers. The human adult wound healing process can be divided into 3 or 4 distinct phases. The process was defined to be having 3 phases – inflammatory, fibroblastic, and maturation <sup>3</sup> and been denoted as inflammatory, was proliferation, and remodeling. 4,5 It was refined in later years to be a 4-phases concept, which was the haemostasis phase, the inflammatory phase, the proliferation phase, and the remodelling phase. <sup>6</sup> In the 3-phases approach, the haemostasis phase was contained within the inflammatory phase. Separate parts of a wound may be at different stages of healing at any one time. <sup>7-10</sup> Several treatment methods have been utilized to improve wound healing process. These include various medical dressings, surgical debridement, topical applications and antiseptic medication. <sup>11,12</sup> Most recent of these methods is Negative Pressure Wound Therapy (NPWT) developed in the early 1990. <sup>13,14</sup> We, therefore, set out to compare the efficacy of negative pressure wound therapy and saline moist gauze dressing in patients admitted with open wounds.

#### MATERIAL AND METHODS

The study was conducted between October 2014 to April 2016. The source of data was patients admitted to the indoor patient care unit of Department of General Surgery of Era's Lucknow Medical College, Lucknow for the management of wounds. The sample size was 104 cases. The study group A consisted of 52 patients who received negative pressure dressing. The group B consisted of 52 patients who received conventional moist dressings.

#### **Inclusion Criteria**

- Patients with acute large wounds (≥ 5 cm in shortest length)
- Patients with chronic, non-healing wounds
   (≥ 1 month duration, ≥ 3 cm in shortest length)

## **Exclusion Criteria**

- Patients with untreated osteomyelitis, Nonenteric and unexplored fistulas, Malignancy in the wound, Exposed vasculature, Exposed nerves, Exposed anastomotic site, Exposed organs
- Patients who did not conform with given treatment
- Age <15 and >75 years
- HIV/HCV/HBsAg positive patients
- Multiple wounds
- Patients receiving Chemotherapy or Radiotherapy
- Moribund patient

 Patient who changed management due to non-medical reasons, patients not completing the prescribed treatment

A predesigned form was used to record the data. Careful history was taken to determine any etiological factors and history of steroid intake or others factors for non-healing wounds. Examination of the wounds was for size (area in centimetre square), depth (in millimetre), presence or absence of dead/devitalized tissue and foreign body, signs of infection and presence or absence of granulation tissue were taken. Also data was collected by recording details of the onset of the wound, progress of the wound and its characteristics with respect to appearance of granulation tissue and percentage of increase along with demographic details. Prior written and informed consent was taken.

#### STATISTICAL ANALYSIS

Data entry and statistical analysis were performed using the Microsoft Excel. The values were represented in number, percentage, mean and standard deviation. Tests of significance were applied to find out the results. Statistical significance taken p value < 0.05.

## **RESULTS**

The 104 patients admitted for the study were divided into two equal and comparable groups. Out of these 104 patients, 52 (50.0%) were subjected to Negative Pressure wound therapy were classified as Group A, and rest 52 (50.0%) were subjected to Saline wet gauze dressing were classified as Group B.(table 1)

**Table 1: Distribution of study population** 

Group	Description	No. of	Percentage
		patients	
Group A	Negative Pressure	52	50.00
	wound therapy		
Group B	Saline wet gauze	52	50.00
	dressing		
Total		104	100.00

Though proportion of patients was higher in Group A as compared to Group B with Diabetic (51.92% vs. 42.31%) and traumatic (15.38% vs. 11.54%) aetiology while proportion of patients in Group B was higher as compared to Group A for necrotising fasciitis/infective (28.85% vs. 21.15%) and pressure

sore (17.31% vs. 11.54%), but difference in aetiology of patients of Group A and Group B was not found be statistically significant (p=0.570).(table 2)

Table 2: Group wise comparison of wound aetiology

Variables	Tot al	Group A (n=52)		Group B (n=52)		Statistica l significa nce	
		No.	%	No.	%	$\chi^2$	p
Diabetic	49	27	51.92	22	42.31	2.	0.5
Necrotising Fasciitis/Inf ective	26	11	21.15	15	28.85	01	70
Pressure sore	15	6	11.54	9	17.31		
Traumatic	14	8	15.38	6	11.54		

Table 3 shows that the mean wound size of Group A (163.28+103.57 cm2) was found to be higher than that of Group B (151.67+88.50 cm2) but this difference was not found to be statistically significant (p=0.540). Though depth of wound of Group A (13.37+6.05 mm) was found to be higher than that of Group B (13.21+5.90 mm) but this difference was not found to be statistically significant (p=0.896).

Table 3: Group wise comparison of wound size (area)

and depth of wounds at presentation

Variables	Group	Mean± SD	P- Value
Wound size	Group A	163.28±103.57	't'=0.614;
(cm <sup>2</sup> )	Group B	151.67±88.50	p=0.540
	Total	157.48±96.04	
Depth of	Group A	13.37±6.05	't'=0.131;
wound (mm)	Group B	13.21±5.90	p=0.896
	Total	13.29±5.94	

Granulation appearance statistically was significantly earlier in Group A (8.35+2.79 days) as compared to Group B (12.52+6.40 days). Wound closure in Group A (23.69+6.52 days) was statistically significantly earlier than in Group B (34.33+10.21 days). Duration of hospital stay in Group A (28.25+6.94 days) was short as compared to that in Group B (39.17+10.36 days), difference in duration of hospital among patients of Group A and Group B was found to be statistically significant. (table 4)

Table 4: Group wise comparison of duration of appearance of granulation, wound closure and hospital stay

Variables	Group A (n=52)		Group B (n=52		Independent 't' test	
	Mean	SD	Mean	SD	't'	'p'
Appearance of	8.35	2.	12.5	6.4	-	< 0.00
granulation		79	2	0	4.310	1
(Days)						
Wound closure	23.6	6.	34.3	10.	-	< 0.00

(Days)		9	52	3	21	6.329	1
Hospital	Stay	28.2	6.	39.1	10.	-	< 0.00
(Days)	-	5	94	7	36	6.319	1

Table 5 illustrates that the difference in wound depth before treatment among patients of Group A (13.37+6.05 mm) and Group B (13.21+5.90 mm) was not found to be statistically significant (p=0.896).Difference in wound depth treatment among patients of Group A (6.13+4.02 mm) and Group B (5.71+4.05 mm) was not found to be statistically significant (p=0.896).Mean reduction in wound depth was 56.86+21.62% in Group A while that in Group B was 58.66+24.54%. Difference in mean reduction in wound depth between Group A and Group B was not found to be statistically significant (p=0.692).(table 5)

Table 5: Group wise comparison of change in wound size and depth

Variables	Group A (n=52)		Grou (n=	-	Independent 't' test		
	Mean	SD	Mean	SD	't'	'p'	
Reduction in Wound size (%)	45.92	5.42	24.07	10.73	13.111	<0.001	
Reduction in Wound depth (%)	56.86	21.62	58.66	24.54	-0.397	0.692	
Duration of wound closure (days)	23.69	6.52	34.33	10.21	-6.329	<0.001	

#### **DISCUSSION**

The concept of moist wound dressings which came into vogue in the 1960s revolutionized wound care. 15 Hydrocolloid dressings remain popular even today. In the early 1990s, the concept of topical negative pressure moist wound dressing was introduced into the field of chronic wound care. This type of dressing involved a combination of hydrocolloid dressings with topical negative pressure dressings. 16 The concept of applying a subatmospheric environment on wounds to accelerate the healing process came into practice in 1993 and was first described by Fleischmann et al. 17 In present study, maximum number of patients had aetiology followed by necrotizing diabetic fasciitis/infective aetiology. The high prevalence of wounds with diabetic aetiology could be attributed to the chronic nature of diabetic wounds. In various studies that included chronic wounds in their study, diabetic aetiology is one of the major contributor. 18-

Statistically the granulation, wound closure and hospital stay durations were significantly shorter in NPWT group as compared to saline group. The findings of study support the view point of Voinchet and Magalon. <sup>22</sup> In present study, granulation tissue formation to be significantly earlier in NPWT group as compared to saline group. However, Braakenburg *et al.* <sup>18</sup> did not find the granulation to be faster in NPWT as compared to control group in overall assessment. In several other studies the rate of granulation has been found to be faster in NPWT group as compared to control group as observed in present study <sup>23-25</sup>. In various studies from India too, NPWT has shown a faster granulation as compared to control group <sup>26-28</sup>. In present study, wound closure time was also achieved nearly 1.5 times faster in NPWT as compared to control group, showing that the rate of granulation corresponded with wound closure too. Although, Braakenburg et al 18 did not find a significant difference in wound healing time between NPWT and control group, Blume et al 29 found wound healing to be 1.52 times faster in NPWT as compared to control group while McCallon et al <sup>30</sup> found it to be 1.87 times faster. Other researchers also found wound healing time to be 1.5 to 2 times faster in NPWT as compared to control group. 31-34 In different studies from India too, wound healing time was reported to be faster in NPWT as compared to control group. In a study comparing NPWT with saline wet-to-moist gauze group, as done in present study, Sinha et al. 28 reported the decrease in wound size to be almost 4 times larger in NPWT group as compared to control group. Ford et al. 35 while comparing NPWT and Health point System (HP) wound gel found reduction in ulcer volume to be higher in NPWT group as compared to HP group but did not find this difference to be significant. In present study, compared NPWT with saline wet-moist gauze and found this difference to be significant. Eginton et al. <sup>36</sup> on the other hand, in a two week assessment reported reduction in wound volume to be 59% and 0% respectively for NPWT and moist gauze dressings. However, in present study we did not achieve these extreme results yet were able to find a substantial difference between NPWT and control groups. Present study show that negative pressure wound therapy is a useful

modality in management of all types of wounds including the chronic wounds.

## **CONCLUSION**

Negative pressure dressing was found to be totally safe, although technically demanding, by virtue of one time application of dressing. Thus, negative pressure moist wound dressing can be considered as a advanced option in the management of chronic wounds. however further studies with a larger population will be needed in the future prior to negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of chronic wounds.

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## STUDY OF MEAN MICRONUTRIENT LEVELS AMONG CHILDREN DIAGNOSED WITH NUTRITIONAL ANAEMIA AT A TERTIARY CARE HOSPITAL OF DISTRICT AZAMGARH

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#### **ABSTRACT**

**Introduction**: Anaemia is a significant public health problem with major consequences for human health and socioeconomic development. Anaemia is an indicator of poor nutrition and poor health developing countries carry the most significant burden of the reported cases of anaemia whose aetiology is often multifactorial. This study was undertaken to assess the mean micronutrients levels in children of nutritional anaemia having Iron, Folate, and Vitamin B12 deficiency.

**Materials and Methods:** This cross sectional study was done in Department of Paediatrics, Government Medical College Azamgarh. Children of age 6 months to 14 years admitted having signs and symptoms of anaemia were included in the study. Sample size calculated was 157. Each case was subjected to Complete Blood Count, General Blood Picture, serum iron, ferritin, folate and vitamin B12 level estimation. Data was analysed using unpaired test, ANOVA and chi square test by using SPSS software version 20 trial.

**Result:** Mean iron level was significantly low in females, rural areas, low socioeconomic status and those malnourished/underweight. Mixed iron, folate and B12 deficiency was found in 48.41%, 30.57% and 22.93% cases respectively. In 24.20% cases no deficiency was found and was classified anaemia due to some unspecified causes. Nearly 31.85% had pure iron deficiency, 12.10% had pure folate deficiency and 10.83% had pure vitamin B12 deficiency. In mixed form of anaemia, iron plus folate, folate plus vitamin B12 and iron plus B12 contributed to 8.92%, 4.46% and 2.55% cases respectively.

**Conclusion:** Nutritional deficiency anaemia is contributing to a large proportion of anaemia patients. More intensified programmes are needed especially for female children, children of rural areas, low socioeconomic status and malnutrition/underweight.

Keywords: Anaemia, micronutrients, iron, folate, B12, malnutrition

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#### INTRODUCTION

According to WHO, anaemia is a widespread public health problem with measure consequences for human health as well as social and economic development. Anaemia is functionally defined as an insufficient RBC mass to adequately deliver oxygen to peripheral tissue. According to WHO data on 'Global prevalence of anaemia 2011', anaemia affects 273.2 million children of age 6 months to 59 months, which corresponds to 42.6% of the total children<sup>1,2</sup>. population of the Nutritional deficiencies are the primary cause of anaemia. Anaemia of nutritional origin is an acquired problem caused by diet that lacks sufficient quantity of bioavailable essential hematopoietic nutrients to meet the need for haemoglobin and red blood cell synthesis. Fourty two percent of the causes of anaemia in children are attributable to iron deficiency. India has a mean haemoglobin concentration of 10.6 gram/dl in children of age 6 months to 59 months, which already comes under the category of mild anaemia<sup>1,2</sup>. WHO and UNICEF therefore re-emphasize the urgent need to combat anaemia and stress the importance of recognizing its multifactorial etiology for developing effective control programs. The aim of this study was to evaluate Iron, vitamin B12 and folate deficiency in children with anaemia and to study the mean

micronutrient levels in children of nutritional anaemia having iron, folate, and vitamin B12 deficiency.

## MATERIAL AND METHODS

This cross sectional study was done in department of paediatrics, GMC Azamgarh.

Children of age 6 months to 14 years admitted in department of paediatrics, having signs and symptoms of anaemia during November 2016 to March 2018 were included in the study.

The sample size was calculated using the formula  $\mathbf{n} = \mathbf{Z2P}$  (1-q)/ d2. d is the 'allowable error of prevalence' which was taken as 10%. Prevalence was obtained from National family health survey-3 (NFHS 3) data of Uttar Pradesh <sup>2</sup>, which was 73.9%. Sample size calculated by 157. This study was approved by ethical committee of the institute. Subjects were included in the study after taking informed consent from the patient/guardian.

In this study we excluded the children who had received iron, folate vitamin B12 therapy, blood transfusion in immediate past, patient diagnosed with other pathological anaemia and seriously sick children. After taking detailed history and clinical examination, 5ml of blood sample was collected through venepuncture and the sample was divided into two parts, E.D.T.A. sample were subjected to complete blood count (CBC) and general blood picture (GBP), and the serum sample were stored at- 200 degree Celsius in cryovials for the estimation of serum iron, ferritin, folate and vitamin B12. Iron estimation was done using calorimetric method with ferrozine without deproteinization. Ferritin estimation was done by particle enhanced essay. immunoturbidimetric Vitamin estimation was based on competitive test principal using intrinsic factor specific for vitamin B12. Folate essay based on a competitive test principle using natural folate binding protein (FBP) specific for folate. Cut of value for serum iron, ferritin, folate and vitamin B12 are 30 microgram/dl, 15 ng/ml, 5.0ng/ml and 200pg/ml respectively. If the serum sample were not having any deficiency of iron, ferritin folate and vitamin B12 were diagnosed as anaemia due to some unspecified causes. We had employed the student unpaired test and analysis of variance (ANOVA) for quantitative data and chi

square test for quantitative data analysis by using SPSS version 20 trial.

#### RESULTS

Socio-demographic profile of this patient has been shown in table-1. Among these 157 children, 52.87% were males and 47.13% were females. The percent proportion of anaemia was more among toddlers (27.39%) and lowest among adolescents (10.83%). Majority belonged to urban areas were 65.6% as compared to 34.4% of rural area. A higher proportion belonged to middle (47.13%) followed by lower (35.67%) socioeconomic status as per Kuppuswamy's classification. Maximum cases belonged to severe (31.84%) followed by moderate (28.66%)and mild (19.05%)grade undernutrition or underweight as per WHO classification of malnutrition/underweight. Out of all anemic causes, 57.96% cases were of moderate grade of anaemia, 38.21% were of severe and 3.82% were of mild grade of anaemia. In general blood picture maximum were of microcytic hypochromic (31.85%) followed by microcytic hypochronic (24.20%), dimorphic (23.57%) and normocytic normochromic (20.83%).deficiency was present in 90% of the cases having microcytic and 83.7% cases of dimorphic general blood picture. Folate deficiency was observed in 47.37% cases, which was of microcytic general blood picture and 40.54% cases of dimorphic general blood picture. National vitamin B12 deficiency found in 48.65% dimorphic followed by 36.84% macrocytic, 25% normocytic and 16% microcytic general blood picture cases.

## DISCUSSION

There was decrease in prevalence of anaemia with the increase in age and these findings are similar to the study done by Rajaratnam et al in Tamil Nadu<sup>3</sup>. This is probably due to the reason that early age group children were maximally dependent on their care providers for their nutrition.

In present study, males were slightly more than females. This is similar to the study done by Gomber et al<sup>4</sup>. Iron and ferritin levels were significantly low in females along with low level of folate and vitamin B12. It can be because of poor attitude towards female child health and nutrition in

our society. In this study almost two third of cases belonged to urban area. Health care facilities are usually easily accessible in urban areas and this can be attributed to the increase in the number of urban patients. This is in accordance with several studies done in the past<sup>5,6</sup>. Mean micronutrient levels were compared between urban and rural subgroup. Rural significant has statistically deficiency. Though the level of ferritin, vitamin B12 and folate were also low in rural population but difference was not statistically significant. This can be attributed to the poor nutritional care in the rural population. In our study anaemia was more prevalent among cases of middle and low socioeconomic status. Several studies done in South East Asia also showed similar results<sup>7,8</sup>. Prevalence of anaemia was graded on the basic of specific nutrient deficiencies in different socioeconomic groups and it was found that iron deficiency and anaemia was more in low middle socioeconomic status. Cobalamin and folate deficiency was also more prevalent in the low and middle socioeconomic status group. Mean level was significantly low in low socioeconomic status, though the mean micronutrient level of ferritin, folate and B12 were also low in the low socioeconomic status but were not statistically significant. This finding is supported by the study on adolescent girls in Korea, where there was a relationship between household income and ferritin level for iron deficiency anaemia. 9 In our study 80.25% anaemic cases had some grade of malnutrition/underweight and only 19.75% of cases had normal nutrition, this is in accordance with study done in Northern Himalayan state India and Bihar where anemic cases suffered from different grades of malnutrition/underweight. 10,11 micronutrient level for iron was significantly low in of malnutrition/underweight grades compared to children with normal nutritional status. The level of ferritin, folate and vitamin B12 were also low different grades malnutrition/underweight but difference was not statistically significant. Among 157 anaemic cases, prevalence of moderate anaemia was highest followed by severe and mild. Similar results were found in other studies done in past. The reason behind this may be that these studies included only

hospitalised cases. <sup>6</sup> In present studies maximum microcytic percentage were of of cases hypochromic general blood picture (31.85%) followed by microcytic (24.20%), dimorphic (23.57%) and normocytic normochromic blood picture (20.38%). The finding is similar to other study done in past in which they found that in maximum cases general blood picture was of microcytic hypochromic type<sup>10</sup>. In the present study, pure or mixed iron deficiency had the highest prevalence (48.41%). Prevalence of iron deficiency was commonest in studies done in past 12,4. Pure or mixed folate deficiency was around 30.57% and contributed to the second most common cause of nutritional deficiency anemia and this was in accordance with Mamobolo et al who found folate deficiency anemia was the second most common cause of nutritional deficiency anemia<sup>10</sup>. In present studies vitamin B12 or cobalamine (22.93%) deficiency was least common cause of nutritional deficiency anemia. The study was similar to other studies in which they found vitamin B12 deficiency was the least common cause of anemia<sup>14</sup>. Variation in the causes of anemia and micronutrient levels in different studies may be contributed to either selection of age group or demographical and geographical reasons. Children with unspecified anemia (24.20%) in whom deficiency of iron, folate and vitamin B12 was found, maximum number belonged to high and middle socioeconomic status had moderate to severe grades of anemia and normocytic normochromic blood picture. This may due to coexisting disease such as malaria, worm infestation, hemoglobinopathies and intake of haematinics, any undiagnosed chronic disease, haemolytic, thyroid disorders, liver disorders and renal disorders 15,16,17.

## **CONCLUSION**

Nutritional deficiency anemia is still observed among a large proportion of the anemic patients. In spite of large scale supplementation with iron and folate, this deficiency is still prevalent, so the strengthening of same is required. Vitamin B12 deficiency is also common in children. Large proportion of the pediatric population is vegetarian so supplementation and fortification of vitamin B12 is also required to reduce the prevalence of anemia.

Table-1 Demographic profile and micronutrient deficiency in children with anemia

<b>Demographical Factors</b>	1	N=157	Iron Deficiency N=76	Folate Deficiency N=48	Vitamin B12 Deficiency N=36
Age Group	Infant	18(11.47%)	6(7.89%)	4(8.33%)	6(16.67%)
	Toddler	43 (27.39%)	23(30.26%)	14(29.17%)	8(22.22%)
	Pre-School	38(24.20%)	19(25%)	12(25%)	10(27.78)
	Adolescent	17(10.83%)	8(10.53%)	8(16.67%)	3(8.33%)
Sex	Male	83(52.87)	43(56.87%)	24(50%)	21(58.33%)
	Female	74(47.13%)	33(43.42%)	24(50%)	15(41.67%)
Residency	Urban	103(65.6%)	33(43.42%)	18(37.50%)	10(27.78%)
	Rural	54(34.4%)	43(56.58%)	30(62.50%)	26(72.22%)
Socioeconomic Status	Upper	27(17.20%)	3(3.95%)	5(10.42%)	5(13.89%)
	Middle	74(47.13%)	33(43.42%)	16(33.33%)	18(50%)
Underweight/	Mild	31(19.75%)	15(19.74%)	5(10.42%)	6(15.67%)
Undernutrition	Moderate	45(28.66%)	22(28.95%)	18(37.5%)	14(38.89%)
	Severe	50(31.84%)	34(44.74%)	19(39.58%)	11(30.55%)
	Normal	31(19.75%)	56.58	6(12.5%)	5(13.89%)
Grades of	Mild	6(3.82%)	3(50%)	2(33.33%)	1(16.67%)
Anemia	Moderate	91(57.96%)	47(51.65%)	28(30.77%)	23(25.27%)
	Severe	60(38.21%)	26(43.33%)	18(30%)	12(20%)
General	Microcytic Hypochromic	50(31.85%)	45(90%)	0	8(16%)
Blood	Macrocytic Hyprochromic	38 (24.20%)	0	18(47.37%)	14(36.84%)
Picture	Dimorphic	37(23.57%)	31(83.78%)	15(40.54%)	18(48.65%)
	Normocytic Normochromic	32(20.83%)	0	3(9.38%)	8(25%)

Table-2: Mean Micronutrients Level and Their Correlation with Demographic Profile.

Demographical factors		Iron Deficienc	y Anemia			Folate Deficiency Anemia		Vitamin B12 deficency Anemia	
		Iron	P	Ferritin Mean±	P	Folate Mean	P	B12 Mean±	P
		Mean±SD (mg/L)	Value	SD (meg/dl)	Value	± SD (meg/dl)	Value	SD (eg/dl)	Value
Age Group	Infant	0.19±0.1	.333	19.79±32.56	.682	3.41±1.72		54.84±23.50	0.284
	Toddler	0.15±0.08		7.29±4.68		3.91±2.83		55.08±24.34	
	Pre- School	0.32±0.51		33.30±120.18		3.64±1.57		44.69±21.34	
	School Going	0.19±0.09		10.43±10.51		3.75±1.16		52.17±26.63	
	Adolesent	0.18±0.10	1	8.38±0.10		4.02±2.44		48.11±16.78	
Sex	Male	0.25±0.16	0.0094	21.18+8174	0.0001	4.22±2.44	0.1253	51.59±20.32	0.8861
	Female	0.18±0.17	1	9.28±8.66		3.31±1.46		50.43±25.87	
Residency	Urban	0.19±0.10	0.0415	10.33±22.3	0.4916	3.03±1.66	0.0674	58.43±25.87	0.6776
	Rural	0.25±0.1		13.32±12.33		4.07±2.15		67.85±51.34	
Socioeconomic Status	Upper	0.27±0.05	0.031	20.84±4.05	0.956	4.04±1.52	0.079	48.41±18.18	0.976
	Middle	0.23±0.08		10.35±15.44		3.86±0.94		46.36±22.10	
	Lower	0.19±0.07		9.87±83.03		2.53±2.52		45.80±25.03	
Nutrition Status Under-	Mild	0.18±0.09	0.006	12.90±22.37	0.486	3.48±139	0.603	62.40±28.37	0.516
Weight Or	Moderate	0.17±0.18		10.38±111.93		3.45±1.56		52.64±20.20	
Undernutrition	Severe	0.12±0.08		7.93±4.65		3.23±2.76		49.52±25.16	
	Normal	0.32±0.08		14.33±3.82		4.55±0.72		64.20±8.35	

Table-3: Etiological distribution of anemia among the study participants.

Type of anemia	Number of children (n=157%)	95% confidence interval%
Pure Iron deficiency	50(31.85%)	24.16-40.54
Pure Folate deficiency	19(12.10%)	9.24-15.34
Pure Vitamin B12deficiency	17(10.83%)	9.12-13.45
Iron plus Folte deficiency	14(8.92%)	7.01-10.45
Folate plus Vitamin B12 deficiency	7(4.46%)	3.55-5.45
Iron plus B12 deficiency	4(2.55%)	1.22-6.45
Iron plus Folate plus Vitamin B12 deficiency	8(5.10%)	3.67-5.96
Unspecified	38(24.20%)	15.78-38.87
Total	157(100%)	

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## MATERNAL FACTORS FOR LOW BIRTH WEIGHT: A COMMUNITY BASED PROSPECTIVE STUDY IN A RURAL AREA OF PANIPAT

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## **ABSTRACT**

**Introduction:** Birth weight is an important gauge of maternal and foetal health as well as an important determinant of morbidity and mortality in infancy. This study was undertaken to find out the sociodemographic and maternal factors associated with low birth weight (LBW) babies.

**Material & Methods:** The present community based prospective study was conducted for a period of two years from January 2017 to December 2018 in selected five villages of Panipat. Total number of 292 live births taken into the study. A written informed consent was obtained. Information pertaining to mothers was collected by interviewing them with the help of predesigned and pretested interview schedule and anthropometric measurements were taken by standard technique.

**Results:** The mean  $\pm$  SD birth weight of the newborn was 2725  $\pm$  425.55 grams. Incidence of LBW was 20.5 %. Joint family, education below high school, lower socio-economic status (SES), maternal height (<145cm) & weight (<45 kg), number of antenatal care (ANC)visits(<4) and less than 100 Iron Folic Acid (IFA) tablets intake were significantly associated with LBW

**Conclusion:** The study concludes that economic, educational and occupational status of mother and her anthropometric values have effect on birth weight of babies. So, health education about nutrition and health of mother are must. Proper ANC and IFA intake to avoid anaemia during pregnancy can reduce risk of newborns with LBW.

Key words: Low birth weight, Maternal factors, Iron Folic Acid, Ante-natal Care

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## INTRODUCTION

Birth weight is an important gauge of maternal and foetal health as well as an important determinant of morbidity and mortality in infancy. Low birth weight (LBW) is one of the most serious challenges in both developed and developing countries. Every year, an estimated 2.5 million newborns die during the first 28 days of life. Approximately 80% of these newborns who die every year are LBW, under 2500 gm.<sup>1-3</sup> India has 25 million births annually and accounts for nearly 25% of global newborn deaths.<sup>3</sup> It is the single most important factor that determines the chances of child survival. Studies found that genetic factors, socio-demographic factors. obstetrics factors, maternal anthropometry, ante natal care, bad obstetric history and maternal illness during pregnancy are significant determinants of

neonatal morbidity such as LBW. 4-8 The other factors significantly associated were extreme maternal age and shorter inter-pregnancy interval.<sup>8,9</sup> The identification of factors contributing to LBW are therefore of considerable importance. In spite of several programmes addressing LBW, it still remains an important public health problem in India. There are many studies conducted previously at various places but most of them are hospital based. Very few are community and rural based studies, so, this study was conducted in the Rural Health Training Centre (RHTC) of Department of Community Medicine, NC Medical College, District Panipat to find out the socio-demographic and maternal factors associated with low birth weight babies.

## **MATERIAL & METHODS**

The present community based prospective study was conducted for a period of two years from January 2017 to December 2018. Permission of institutional ethics committee was taken. The study was conducted in all five villages (Adiyana, Atawla, Alupur, Ahar and Urlana) covered under RHTC, Adiyana which are the field practice areas of the Department of Community Medicine, NC Medical college having population of 30000.Of 304pregnant women registered between January 2017 to April 2018 at Antenatal Clinic, RHTC, Adiyana 292 were included in the study. The mothers who could not be followed and who did not give live births and those who did not give written consent were excluded from the study. Written informed consent was obtained. The main outcome variable was LBW, defined as birth weight of less than 2500 grams. Maternal characteristics like age, caste, education, occupation, number of antenatal care (ANC) visits and number of Iron Folic Acid (IFA) tablets consumed during pregnancy, and parity were obtained from the study subjects by interviewing them with the help of predesigned and pretested interview schedule. They were subjected to anthropometric measurements. Weight of women was measured using standard technique with a weighing machine having an accuracy of 0.1 kg. Height of the mothers was measured following standard technique using a steel anthropometric rod with parallel bar having accuracy of 0.1 cm. Mothers were paid home visit too at the time convenient to them and particulars about socioeconomic factors verified. Regular follow up was done. Mothers requiring special investigations and treatment were taken to NC Medical College. Mothers were visited at the time of delivery and particulars about new born were recorded. Data were analysed using R statistical software version 3.53. The results were described in terms of mean and standard deviation for continuous variables, and categorical variables were presented in form of proportion. For the frequency and testing association between LBW and risk factors, Chisquare test was used and p < 0.05 was considered to be statistically significant.

## **RESULTS**

The mean  $\pm$  SD birth weight of the newborn was 2725  $\pm$  425.55 grams. Incidence of LBW was 20.5%. Incidence of LBW was 17.3% in males and 24.3% in females, however this difference was statistically insignificant( $\gamma$ 2= 2.15, p = 0.14).

Table 1 exhibits the association between maternal socio-demographic characteristics with birth weight. No association of LBW was found with age

and caste of the mother. Mothers who belonged to joint family had higher proportion of infants with LBW as compared to those who belonged to nuclear family (23.5% versus 14.6% respectively). Compared to 17.2% LBW in women with education of high school and above, the incidence of LBW was 27.3% in subjects educated below high school and the differences were statistically significant (p=0.03). The percentage of LBW was maximum (26.8%) in labourers followed by 11.0% in homemakers and 9.1% in mothers in service and were found to be significant (p=0.001). Incidence of LBW was 27.4% and 13.7% in study subjects above and below median economic status respectively (p=0.003).

Table 1: Association of maternal socio-demographic characteristics with birth weight

characteristics with birth weight									
Variables	Low	Normal	Total	Chi-square					
	Birth	Birth		test					
	Weight	Weight							
	N (%)	N (%)							
Age (years)									
< 20	7 (19.4)	29 (80.6)	36	$\chi 2 = 0.42$					
21-25	38 (20.2)	150(79.8)	188	df=3					
26-30	10 (20.4)	39 (79.6)	49	p=0.93					
>30	5 (26.3)	14 (6.0)	19						
Caste									
Others	35 (20.6)	135 (79.4)	170	$\chi 2 = 0.001$					
OBC/SC	25 (20.5)	97 (79.5)	122	df=1					
				p=0.98					
Type of									
family									
Nuclear	14 (14.6)	82 (85.4)	96	χ2=3.11					
Joint	46 (23.5)	150 (76.5)	196	df=1					
				p=0.07					
Education									
≥ High school	34 (17.2)	164 (82.8)	198	χ2=4.92					
< High school	26 (27.3)	68 (72.3)	94	df=1					
				P=0.03					
Occupation									
Housemaker	10 (11.0)	81 (89.0)	91	χ2=11.16					
Laborer	48 (26.8)	131 (73.2)	179	df=2					
Service	2 (9.1)	20 (90.9)	22	P=0.003					
Economic									
status									
Above median	20 (13.7)	126 (86.3)	146	$\chi 2 = 8.39$					
Below median	40 (27.4)	106 (70.6)	146	df=1					
				P=0.003					
L	1		1	l					

Table 2 exhibits the association between maternal characteristics with birth weight. The incidence of LBW in mothers of height (<145) cm was 54.5% in comparison to 16.2% in the subjects of height ( $\geq145$ cm) and was statistically significant (p=.001). More than half (62.5%) of the mothers less than 45 kg delivered LBW newborns while only 15.4% mothers with weight  $\geq 45$ kg delivered LBW newborns (p=0.001). Mother with BMI <16 were at risk to have low birth weight babies when compared

with mothers having BMI>18.5 but difference was insignificant. LBW was more common in first order babies than with parity second or more. LBW babies were significantly more (24.7%) to the mothers who received less than four antenatal visits in comparison to those who received four or more ante natal visits where LBW babies were 14.0%. Mother who consumed less than 100 IFA tablets during pregnancy experienced more LBW babies 54.5% as compare to mothers who consumed 100 or more IFA tablets in which LBW were 12.7% which was again statically significant (P=0.001).

Table 2: Association of maternal factors with birth weight

Variables	Low	Normal	Total	Chi-
	Birth	Birth		square
	Weight	Weight		test
	N (%)	N (%)		
Maternal				
height				
≤ 145 cms	42 (16.2)	217 (83.8)	259	$\chi 2 = 26.3$
< 145 cms	18 (54.5)	15 (45.5)	33	df=1
				p=0.001
Maternal				
weight				
≥ 45 kgs	40 (15.4)	220 (84.6)	260	$\chi 2 = 38.7$
< 45 kgs	20 (62.5)	12 (37.5)	32	df=1
				p=0.001
Maternal				
BMI				
> 18.5	41 (20.8)	156 (79.2)	197	$\chi 2 = 0.51$
16-18.5	15 (18.8)	65 (81.2)	80	df=2
< 16.0	4 (26.7)	11 (73.3)	15	P=0.77
Maternal				
parity				
≥ Second	25 (16.8)	124 (83.2)	149	$\chi 2 = 2.64$
First	35 (24.5)	108 (75.5)	143	df=1
				P=0.1
ANC visits				
≥ 4	16 (14.0)	98 (86.0)	114	χ2=4.8
< 4	44 (24.7	134 (75.3)	178	df=1
				P=0.03
IFA tablets		l		
intake				
≥100	30 (12.7)	207 (87.3)	237	χ2=47.9
< 100	30 (54.5)	25 (45.5)	55	df=1
	,			P=0.001

## DISCUSSION

The mean ± SD birth weight of the newborn was found to be 2725 ± 425.55 grams, similar to the findings of earlier studies. 8,10 In our study the incidence of LBW was found to be 20.5% which was more among females (24.3%) than in male babies (17.3%) which is very close to other rural study in India. No significant association between maternal age and LBW was found also reported by various studies. 5,6,12 However, pregnancy after 30 years need better care to prevent LBW. Caste wise incidence of LBW was also measured in this study,

which was found insignificant. Similar results were reported by other studies. 13,14 In this study LBW were higher (23.4%) among mothers living in joint families compare to mothers in nuclear families which was 14.6%. Bhattacharjya et al<sup>15</sup> and Dasgupta et al<sup>16</sup> and also found higher LBW among mothers living in joint families. In our findings, low educational status and low anthropometric values of mother were found risk factors for LBW babies which was in accordance with the other studies. 5,6,8,9 This might be due to the fact that families with higher education could have better access to health facilities. However, the present study findings are not in confirmation with a study in which illiteracy did not seem to have effect on weight of newborn. This also indicates the need for promotion nutritional counselling during pregnancy prevent LBW. Mothers occupation significantly associated with birth weight of babies too. Labourers mothers were having more (26.8%) LBW babies compare to housewives and service class mothers and for them it was 11.1% and 9.1% respectively. Anand et al and Sunilbala et al in their studies revealed similar observations. 6, 17 LBW was 13.7% in those above median per capita income group compared to 27.4% in below median income group. This factor was found significant and similar findings have been reported in other study. <sup>17</sup>This could be due to the indirect effect of income, which access favours better to nutrition during pregnancy. This finding may be also alarm for health officials to improve the quality of prenatal services for the poor sections of the society. A higher number of LBW babies were born to mothers who had less than four ANC visits. Similar findings were reported by earlier studies.<sup>9,11</sup>The current study revealed no significant association between birth weight of first order babies as compared to babies who had birth order two and more which is in contrasts with other studies. 11,12 This might be due to the effect of placental factors. The association between birth weight and IFA intake was statistically significant in the current study. LBW babies born to mothers who consumed less than 100 IFA tablets were 54.5% as compared to mothers who consumed more than 100 IFA tablets which was 12.7%. Dasgupta et al and Kandhaswami et al observed that odds of having LBW was twice among mothers who inadequately used IFA tablets. 16,18

## **CONCLUSION**

Economic, educational and occupational status of mother and her anthropometric values have effect on birth weight of babies. So, health education about nutrition and health of mother are must to have healthy babies. Proper Ante-natal care and IFA intake to prevent anaemia during pregnancy can reduce risk of LBW babies. Thus, emphasis should be given on improving ante-natal coverage and quality of services.

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## CLINICO-RADIOLOGICAL PROFILE OF ACUTE ABDOMEN AND ITS IMPACT ON TREATMENT

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## **ABSTRACT**

**Introduction:** Acute abdomen refers to a sudden, severe abdominal pain due to intra- abdominal diseases. It is medical emergency. Very often, an accurate diagnosis cannot be made without surgery and many wonders are revealed on opening the abdomen. Imaging plays an important role in diagnosis and treatment of patients. The aim of present study was to make immediate diagnosis, with the help of different imaging techniques, so as to minimize mortality and morbidity.

**Material and Methods:** The study was conducted in 75 patients of acute abdomen, admitted in Pt. Ram Prasad Bismil Hospital, affiliated to Autonomous State Medical College, Shahjahanpur from November 2018 to October 2019. The clinico- radiological profile of acute abdomen and its impact on treatment was observed. Prior approval from the Institutional Ethics Committee was obtained.

**Results:** The causes of acute abdomen in our study were intestinal perforation (32%), acute appendicitis (21.3%), acute cholecystitis (16%), and acute intestinal obstruction (13.3%), torsion of ovarian cyst (9.3%), renal or ureteric calculi (5.3%) and acute pancreatitis (2.6%). We used different imaging modalities like X-ray chest PA view (92%), X -ray abdomen in standing (45.3%), X-ray abdomen KUB (5.3%), USG abdomen (46.6%), and CT scan abdomen (36%) to make accurate diagnosis. Out of total study patients, 84 % were managed by surgical treatment and 16% by conservative treatment.

**Conclusion:** In our study, maximum number of patients were of intestinal perforation followed by acute appendicitis, acute cholecystitis, and acute intestinal obstruction, torsion of ovarian cyst, renal or ureteric calculi and acute pancreatitis. Out of total seventy five study subjects, 63 cases were managed by surgery and rest by conservative treatment. There were 4 mortalities and 15 post- operative complications in the study. The role of CT scan in acute appendicitis and acute pancreatitis was superb. However, in cholecystitis and renal stones USG remained as the primary imaging technique.

Keywords: Acute abdomen, Conventional radiography, Imaging modalities, mortality, morbidity

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## INTRODUCTION

Acute abdomen refers to a sudden, severe abdominal pain which reveals symptoms and signs of intra abdominal diseases. So, it demands an urgent attention and treatment. According to Silen W Copes<sup>1</sup>, acute abdominal pain is still a common problem whose missed diagnosis can result in quick death so immediate diagnosis should be made. The acute abdomen may be caused by infection, inflammation, vascular occlusion or obstruction. The diagnosis of an acute abdomen is further complicated by relative lack of physical findings. This further emphasizes the need for rapid diagnosis. <sup>2</sup> Several cases need immediate surgical treatment. However, some cases related with acute abdomen do not need surgical intervention. The patients of acute abdomen require timely decision about the need of surgery, if any. Of all patients presenting to emergency department, approximately 7% to 10% have complaints of acute abdominal pain. Formerly, these patients were thought to have acute abdomen and surgery was indicated. Nowa-days patients with acute abdominal pain, even if accompanied by abdominal tenderness and rigidity, not of them will undergo surgery, while others without abdominal rigidity are operated on. Now-a-days, diagnostic imaging is widely used in work up of patients with acute abdominal pain. U.S.G., C.T. Scan abdomen and X-rays are frequently used on top of clinical and laboratory evaluation. Performing C.T. Scan is most important because it facilitates an accurate diagnosis in urgent condition. C.T. Scan therefore be considered for primary technique for diagnosis of acute abdominal pain.<sup>3</sup> The use of conventional

radiography has been surpassed. This technique has only a possible role in diagnosis of bowel obstruction and perforation. However, CT scan of small bowel obstruction has got value in establishing the diagnosis and determining the degree and cause.4 The American College of Radiology suggests an abdomen /pelvic CT with contrast medium in patients of acute abdomen. While others are in favor of USG as the primary imaging technique, mainly because USG is easily accessible and does not expose patients to ionizing radiation. Ionizing radiation due to CT is associated with risk of radiation induced cancer, especially in young patients <sup>5</sup>. This is the drawback of CT, especially as CT is increasingly being used in diagnostic work up of young patients. This may prompt the evaluation of alternative imaging strategies next to CT. such as MRI. However, diagnosis should not be missed or delayed and so the most accurate and reliable imaging technique should be used. So, after the thorough clinical examination and proper imaging technique, we can make the accurate diagnosis in more than 90% of the patients of acute abdomen. This, in turn, facilitates proper treatment whether surgical or conservative, accordingly and thus, mortality and morbidity of such patients can be minimized. This study was conducted to describe the clinico-radiological profile of acute abdomen and its impact on treatment in admitted patients of Pt. Ram Prasad Bismil Hospital, affiliated with Medical Autonomous State College, Shahjahanpur from November 2018 to October 2019. Seventy-five patients were selected for this study.

# **MATERIAL AND METHODS**

This present study includes observation on clinico-radiological profile of acute abdomen and its impact on treatment in 75 patients of acute abdomen admitted in Pt. Ram Prasad Bismil Hospital affiliated with Autonomous State Medical College, Shahjahanpur from November 2018 to October 2019. The selected patients of acute abdomen include intestinal perforation, acute appendicitis, acute cholecystitis, acute intestinal obstruction, torsion of ovarian cyst, renal or ureteric calculi and acute pancreatitis. Out of these, 63 patients were managed surgically and 12 patients were managed by conservative treatment. A written consent from all selected patients and institutional ethics committee approval was obtained.

#### **Inclusion Criteria**

- 1. Patients willing to participate in this study.
- 2. Patients with history of acute abdominal pain.
- 3. Positive findings in imaging techniques.

#### **Exclusion Criteria**

Traumatic and Cardiac Cases were excluded

# Investigations

# **Imaging Techniques**

- 1. X-Rays: Chest PA View as routine, Abdomen in sitting posture and Abdomen KUB
- 2. U.S.G. Abdomen
- 3. C.E.C.T. Abdomen

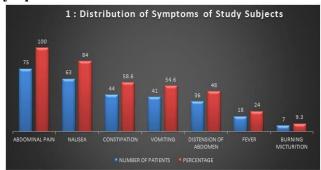
#### **Treatment**

Patients were taken up for immediate surgery accordingly, however some patients were kept on conservative treatment. Our main aim was to make an immediate diagnosis of acute abdomen with the help of clinical and imaging techniques, thus to reduce mortality and morbidity.

#### **RESULTS**

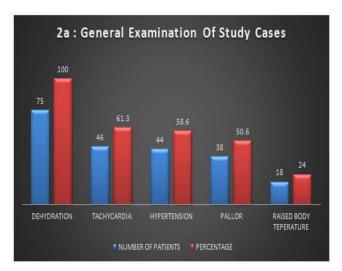
The study comprised of 75 cases of acute abdomen admitted in Pt. Ram Prasad Bismil Hospital affiliated with Autonomous State Medical College Shahjahanpur from November 2018 to October 2019. The selected patients include intestinal perforation (32%), acute appendicitis (21.3%), acute cholecystitis (16%), acute intestinal obstruction (13.3%), torsion of ovarian cyst (9.3%), renal or ureteric calculi (5.3%) and acute pancreatitis (2.6%). Out of these, 63 patients were managed surgically and 12 patients were managed by conservative treatment. This is explained via graphical statistics.

# 1: Distribution of study subjects according to symptoms

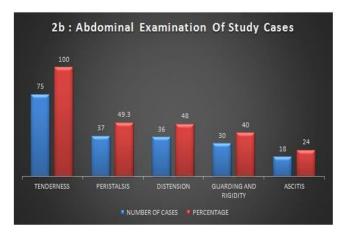


Abdominal pain was the most common symptom (100%) followed by nausea (84%).

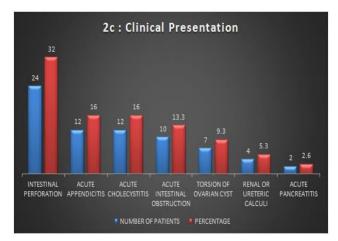
# 2: Distribution of study cases according to general, abdominal and clinical presentation



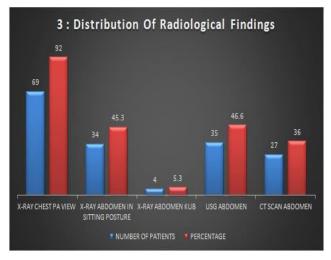
Dehydration was the most common symptom found among the study patients (Figure 2a)



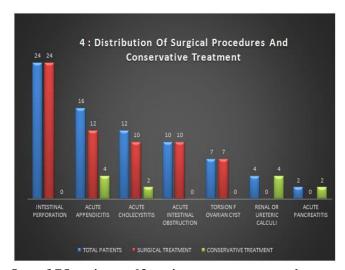
Majority (100%) of cases had abdominal tenderness on examination. (Table 2b)



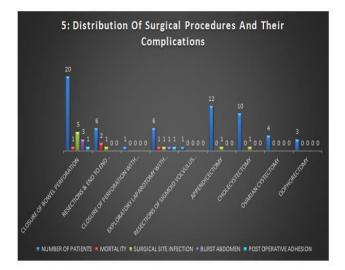
Intestinal perforation (32%) was the most common clinical presentation observed. (Table 2c)



X-Ray Chest PA View was done in majority (92%) of patients (Table 3)



Out of 75 patients, 63 patients were managed surgically and 12 patients were managed by conservative treatment (Table 4).



There were 4 mortalities, and 15 post-operative complications observed in study cases (Figure 5).

#### DISCUSSION

Earlier the surgery better is the prognosis. In our study, Intestinal perforation was on top of list, followed by Acute Appendectomy, Acute Cholecystitis, Acute Intestinal Obstruction, Torsion of Ovarian Cyst, Renal or Ureteric Calculi and Acute Pancreatitis. Imaging plays as an important role in diagnosis and treatment, because clinical evaluation results can be inaccurate, so correct line of treatment delays.

The American College of Radiology suggests an abdomen/pelvic CT scan with contrast medium in patients of acute abdomen. While others are in favor of USG as the primary imaging technique mainly, because USG is easily accessible and does not expose patients to ionizing radiation.

American College of Radiology recommended different imaging techniques for accessing abdominal pain based on pain location. USG is recommended to assess right upper quadrant pain<sup>6</sup> and CT scan is recommended for right and left lower quadrant pain. For suprapubic region, USG is recommended. The gold standard for the diagnosis of acute appendicitis remains a proper taken history and a thorough conducted clinical examination. However, recently USG and CT abdomen have been described as an accurate diagnostic modalities in patients suspected to have acute appendicitis. Appendiceal CT scan considered to be 98% accurate in diagnosis of acute appendicitis when made by an expert radiologist. Normal W.B.C. does not exclude acute appendicitis. CT Scan is better than USG in acute appendicitis<sup>7</sup>. In acute Pancreatitis, Serum Amylase and Serum Lipase increase more than three times a normal. CT is imaging modality of choice for the diagnosis and staging of acute pancreatitis and also its complications<sup>8</sup>. CT Scan in early assessment of acute pancreatitis shows better prognosis <sup>9</sup>. USG has a 95% sensitivity for detection of Cholecystitis. USG is less useful in diagnosing acalculus cholecystitis with 60-70% sensitivity. Because ovarian torsion often mimics appendicitis, diverticulitis or renal colic, CT rather than USG is often the first modality with which these patients are imaged, even after a thorough clinical evaluation. Plain radiography of the abdomen is often more readily obtainable and less expensive than USG and CT and can be helpful in several circumstances like bowel obstructions and intestinal perforation. It should be a routine investigation in acute abdomen <sup>10</sup>. However, USG and CT abdomen can also be used to diagnose bowel obstruction & perforation. Xray abdomen KUB detects urinary stones. Not all kidney stones are visible on X-ray. Uric acid stones and small kidney stones will not be revealed by a standard X- ray. For these conditions, USG & CT scan abdomen can be used. Ureteral stones usually cannot be seen using USG, unless the stone is located at the junction of ureter and bladder. In general, CT is highly effective at identifying patients with non-specific abdominal pain who need urgent interventions <sup>11</sup>. USG is considered the gold standard method to identity gall stones <sup>12</sup>.

#### **CONCLUSION**

Earlier the treatment, better the prognosis. Diagnostic imaging is widely used in work up of patients with acute abdominal pain. X-ray, USG, CT Scans are frequently used on top of clinical and laboratory evaluation. The role of CT Scan in acute appendicitis and acute pancreatitis was superb. However, in cholecystitis and renal stones USG remained as the primary imaging technique. Imaging plays on important role in diagnosis and treatment of patients, because results of clinical evaluation can be inaccurate, so correct line of thorough treatment delays. After, examination and proper imaging techniques, we can make the accurate diagnosis in more than 90% cases of acute abdomen so as to provide timely proper treatment to the patients. This in turn facilitates proper treatment whether surgical or conservative accordingly and thus, mortality and morbidity of such patients can be minimized.

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# BACTERIOLOGICAL STUDY OF SURGICAL SITE INFECTIONS IN A TERTIARY CARE HOSPITAL OF DISTRICT LUCKNOW

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#### **ABSTRACT**

**Introduction:** Surgical site infections (SSI) comprise a foremost public health problem worldwide and are the second major frequently reported nosocomial infections. They are responsible for increasing the treatment cost, length of hospital stay and significant morbidity and mortality. This study was undertaken to ascertain the bacterial etiology of SSI in humans and to determine antibiotic susceptibility pattern of the isolates.

**Material and Methods:** This cross-sectional study was conducted for a period of six months (January 2019 to June 2019) in the Department of Microbiology at Integral Institute of Medical Sciences and Research, Hospital Lucknow, India. The study was approved by the Ethical Research Committee (ERC) of the institute. Data entry and statistical analysis were performed using the Microsoft Excel.

**Results:** Prevalence of SSI in the present study was 3.12%. Out of 50 samples collected and processed, 39 (83.33%) had pure growth (mono isolate), 2 (4.76%) had two isolates and 1 (2.38%) had polymicrobial growth. Out of 50 samples collected 42 (84%) yielded positive growth. Gram positive isolates were (52.38). Pattern of resistance and sensitivity was noted among coagulase negative staphylococci. Enterococcus exhibited 100% resistance to penicillin in the study.

**Conclusion:** Gram positive organisms were major cause of SSI. Organisms were resistant to commonly used antimicrobial agents, e.g. Penicillin, Ciprofloxacin, Levofloxacin, Tetracycline. Appropriate use of antibiotics and proper aseptic practices can reduce the rate of SSI. This can also reduce major problem of antimicrobial resistance in hospital acquired infections.

**Keywords:** Resistance, surgical site infections, nosocomial infection, post operative wound

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#### **INTRODUCTION**

After urinary tract infection, surgical site infections (SSI) are the most common nosocomial infections in hospitalized patients. <sup>1</sup> As many as 1% of the patients undergoing clean and 11% of patients undergoing clean contaminated surgery experience SSI. <sup>2</sup> There is substantial burden with increased morbidity and exceeding healthcare costs. <sup>3</sup> Despite efforts to control infection and better understanding

of sepsis, wound infection is still a clinical problem and some infections in clean wounds still remain unexplained. <sup>4</sup> In many SSIs, the responsible pathogens originate from patient's endogenous flora. The causative pathogen depends on the type of surgery; the most commonly isolated organisms are Staphylococcus aureus, coagulase negative Staphylococci, Enterococcus spp and E. coli. <sup>5</sup> Staphylococcus aureus is a commonly isolated

organism in SSI, accounting for 15-20% infections occurring in hospitals; other organisms regularly isolated from SSIs. The risk of developing Surgical Site Infection depends on a broad range of factors including age and clinical condition of the patient at the time of the surgery, duration of preoperative stay in the hospital, the type and duration of operative procedure, type of anesthesia, preoperative skin preparation of patient, use of implant and drain and postoperative wound care. Identification of these factors is important for developing preventive measures for SSI. 6,7 Broad spectrum empirical antibiotics are given at many institutes in surgical patients. However, inappropriate use of antibiotics may result in the drug resistant strains. emergence of multi Knowledge of common organisms causing SSI and their susceptibility pattern will help us choose most sensitive antibiotics earlier thus, preventing further life-threatening infections and adding less to the patient's suffering. The present study undertaken to ascertain the bacterial etiology of SSI in humans and to determine antibiotic susceptibility pattern of the isolates from IIMS&R surgical setups.

#### MATERIAL AND METHODS

The present cross sectional study was conducted at Integral Institute of Medical Sciences and Research, Hospital for a period of 6 months from January 2019 - June 2019. The study was approved by the institutional Research committee (IRC) & the Ethical Research Committee (ERC). Before enrollment in the study, written consent was taken from the patients and/or legal guardian of the patients in case of children. All patients of either sex, admitted in departments of Surgery, who had undergone surgical procedures during the study period, were included. Patients and patient's guardians who were not be willing to give consent to participate in the study were excluded. Samples were sent to Microbiology Laboratory for Bacteriological Examination.Clinical history of each patient was recorded as per the proforma. Antibiotics given were also recorded.

**Specimen Collection:** Specimens were collected from the hospital of Integral Institute of Medical Sciences and Research, Lucknow before the start of antimicrobial therapy with a sterile cotton swab.

The deepest part of the wound was sampled, avoiding the superficial microflora. Swabs were well soaked in pus & were collected by a surgical practitioner.

**Gram Staining:** Evenly spread smear of the specimen was made on a clean grease-free glass slide & stained by Gram stain technique.

**Pus Culture** – was put on Nutrient agar, Blood agar& CLED or MacConkey agar as per standard policy protocols. Growth was checked after 24/48 hrs of incubation of cultures at 37C. Identification of isolates was done on the basis of colony morphology, motility, and biochemical tests such as – Catalase, Coagulase, Oxidase, Indole, Methyl red, Voges Proskauer, Urease, Citrate, Triple sugar iron, Nitrate reduction tests, Phenylalanine deaminase test, Oxidation and fermentation, Bile esculin hydrolysis & carbohydrate fermentation tests.

The antimicrobial susceptibility testing was done by Kirby Bauer's disk diffusion method on Mueller Hinton Agar and interpreted as per Clinical Laboratory Standard Institution guidelines (CLSI. 2018) and antibiotics discs were used according to bacterial isolate. <sup>8</sup>

Commercially available antibiotics disc of 6 mm from HI-MEDIA were used in study. After overnight incubation the result was interpreted by comparing the zone of inhibition of test bacterium. The zone size was measure in mm from edge of the disks to the zone edge. It was interpreted as Sensitive, Intermediate and Resistant. Antibiotic discs used as per isolate comprised of penicillin, cefoxitin, methicillin, augmentin, aztreonam, vancomy cin, teicoplanin, amikacin, tetracycline, gentamycin,doxycycline, linezolid, ceftazidime, ciprofloxacin, levofloxacin ,tobramycin, piperacillin/tazobactam, polymyxin B, imipenem and doripenem.

#### **Statistical Analysis**

Data entry and statistical analysis were performed using the Microsoft Excel. The values were represented in number, percentage, and bar diagram.

# **RESULTS**

During the study period a total of 1600 surgeries were conducted and out of them, 50 defined cases of SSI (3.12%) as per CDC guidelines were enrolled in the study. Out of 50 SSI cases, 42 cases were culture positive (84%), while 8 cases were culture negative (16%). The number of surgeries in each department and percentage of infected cases were presented in Table 1.

Table 1: Clinical characteristics of patients with SSI

Variables	No.	%				
Age						
20 years	9	21.42%				
21-40 years	23	54.76%				
> 40 years	10	23.80%				
Sex						
Male	18	42.85%				
Female	24	57.14%				
Surgical department	Surgical department					
General surgery	21	50%				
Obstetrics / Gynecology	5	11.90%				
Orthopedics	12	28.57%				
ENT	4	9.52				

Prevalence of SSI in the present study was 3.12%. 50% were from the general surgery ward, 28.57% from orthopedics unit, 11.90% from the Obstetrics / Gynecology ward and 9.52% from the ENT.The rate of infection were highest in age group between 21- 40 (54.76%, 23/42). Of the 42 patients in the study group, 57.14% were females and 42.85% were males.39 (83.33%) had pure growth (mono isolate), 2 (4.76%) had two isolates and 1 (2.38%) had polymicrobial growth. (table 1)

Figure 1: Percentage of SSI developed in different surgical units

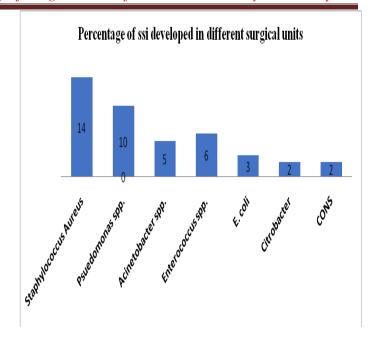


Figure 1 illustrates the Percentage of SSI developed in different surgical units from the samples collected. Out of 50 samples collected 42 (84%) yielded positive growth. The pathogens isolated were *S. aureus* (14 isolates, 33.33%), *Pseudomonas spp.* (10 isolates, 23.80%), *Enterococcus* spp. (6 isolates, 14.28%), *Acinetobacter* spp.(5 isolates, 11.90%), *Escherichia coli* (3 isolates, 7.14%), *Citrobacter* (2 isolates, 4.76%), Coagulase negative *staphylococcus* (2 isolates, 4.76%).

Figure 2: Percent distribution of antibiotics sensitivity in *S. aureus* from samples

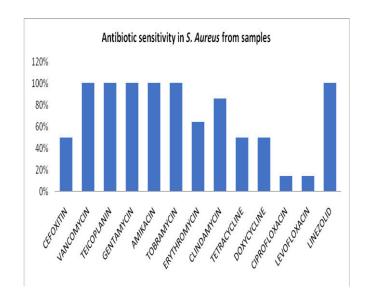


Figure 2 depicts that the percent distribution of antibiotics sensitivity in S. Aureus from samples. Out of 14 strains of S. aureus, 7 were resistant to cefoxitin and confirmed as MRSA. All the strain was resistant to penicillin (100%). Resistance to vancomycin, teicoplanin, gentamycin, amikacin,

tetracycline, doxycycline and linezolid was not identified in the study even in MRSA strains.

Figure 3: Percent distribution of antibiotics sensitivity in *Enterococcus* from samples

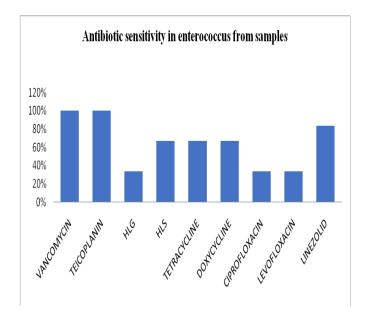


Figure 3represents that the percent distribution of antibiotics sensitivity in enterococcus from samples. In which findings showed that the similar pattern of resistance and sensitivity was noted among coagulase negative *staphylococci.Enterococcus* exhibited 100% resistance to penicillin in the study. None of the isolates were resistant to vancomycin.

Figure 4: Percent distribution of antibiotics sensitivity in *Pseudomonas* from samples

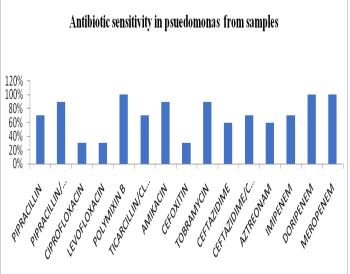


Figure 4 illustrates the percent distribution of antibiotics sensitivity in *Pseudomonas* from samples. In which *Pseudomonas* were moderately sensitive to piperacillin (70%), ceftazidime (60%), tobramycin (90%), cefoxitin (50%), ciprofloxacin

(30%) and all the strain sensitive to piperacillin/tazobactam, polymyxin B, imipenem and doripenem.

Figure 5: Percent distribution of antibiotics sensitivity in *Acinetobacter* from samples

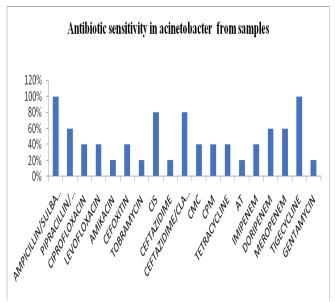


Figure 5shows the percent distribution of antibiotics sensitivity in *Acinetobacter* from samples. Acinetobacter isolated were moderately sensitive to ciprofloxacin (40%), cefoxitin (40%), imipenem (60%), gentamycin (20%) and extensive resistance to amikacin and aztreonam (80%).

Figure 6: Percent distribution of antibiotics sensitivity in *E.coli* and *Citrobacter* from samples

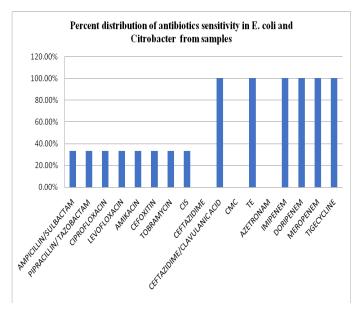


Figure 6 shows that the percent distribution of antibiotics sensitivity in *E.coli* and *Citrobacter* from samples. E. coli was moderately sensitive to

ampicillin (33.33%),levofloxacin (33.33%),amikacin (33.33%),(33.33%),cefoxitin ciprofloxacin (66.66%). All the isolate were sensitive to tetracycline, imipenem, tigecycline. Citrobacter isolated were sensitive to tigecycline (100%) and doripenem (100%) and show resistance to piperacillin, levofloxacin, amikacin, cefoxitin, tobramycin.

#### **DISCUSSION**

The present study was carried out in 1600 patients surgeriesnamely underwent various Appendectomy, Hernia operation, Laparotomy, Mastectomy, Amputation, cholecystectomy and Nephrectomy. The present study shows SSI rate 3.12% which is comparable with rate of SSI reported by Cruse and Foord et al (4.7%). 9 In present study patients were divided in 3 age groups. The rate of SSI was highest (54.76%) in age group 21-40 years which is comparable to other studies. <sup>10.11</sup> This is due to poor immune response, existing co morbidities in old patients and reduced compliance with treatment. Prolonged preoperative hospital stay was associated with higher rate of infection. Prolonged preoperative hospital stay leads colonization with antimicrobial resistant microorganisms and itself directly affects patient's susceptibility to infection either by lowering host resistance or by providing increased opportunity for ultimate bacterial colonization. Ercole et al 12 and Lilani et al 13 also reported higher rate of SSI in patients with prolonged preoperative hospital stay. ASA score is very prescient for development of SSI. In the present study risk of SSI was increased with ASA (American Society of Anesthesiologist) score more than 3 (35.8%). Uchino et al <sup>14</sup> also reported ASA score more than 3 associated with higher rate of SSI. ASA score is related with other factors i.e. diabetes mellitus, obesity, malnutrition, other infection, smoking, etc. Surgical sites were classified using CDC's criteria. Razavi et al. also showed similar results. 15 Our finding of higher rate of SSI with increasing duration of surgery was consistent with finding of other workers. 11,12 The simplest explanation for an increased disease rate with longer method is that a more drawn out introduction time will expand the degree of contamination of the injury and in this way the level of harm to the tissues, and more

prominent weariness among the individuals from careful group will prompt breaks in sterile technique. The rate of SSI also differs from specialist to specialist. The ability and experience of specialist straightforwardly influences the level of contamination of the surgical site through breaks in procedure or coincidental passage in to a viscous. The skills of specialist additionally influences the state of surgical site and in this way its protection from disease. In the present study the rate of SSI was 4.94% in operations performed by junior doctors compared to rate in operations performed by senior consultants (2.24%). Ercole et al 11 also reported higher rate of infection in operations performed by junior doctors. In infection control programs study of risk indices helps in surveillance and control efforts. Observation of careful site diseases with input of proper information to specialists would be attractive to reduce SSI rates.

#### **CONCLUSION**

Gram positive organisms were major cause of SSI. Organisms are resistant to commonly used antimicrobial agents, e.g. Penicillin, Ciprofloxacin, Levofloxacin, Tetracycline. Appropriate use of antibiotics and proper aseptic practices can reduce the rate of SSI. This can also reduce major problem of antimicrobial resistance in hospital acquired infections.

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# IMPACT OF CONTINUOUS RENAL REPLACEMENT THERAPY AMONG CRITICALLY ILL SEPTIC ACUTE KIDNEY INJURY PATIENTS

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#### **ABSTRACT**

**Introduction:** Sepsis is the leading cause of acute kidney injury (AKI) treated with renal replacement therapy (RRT) in critically ill patients. AKI is a common and serious complication in critically ill patients, and the development of AKI increases morbidity and mortality in these patients. The present study has examined the impact in the timing of CRRT application on outcome of sepsis patients with AKI and also examined the early start of CRRT within 6hrs of maximum hemodynamic stabilization among the sepsis patients with AKI.

**Material and Methods:** This 15 months prospective study included critically ill septic patients aged above 18 years with acute kidney injury admitted in department of anesthesiology and critical care medicine, B.R.D. Medical College & Nehru Hospital, Gorakhpur, U.P. (India). A total 24 patients were randomly divided into two groups: Group I (NO CRRT) Group II (CRRT) of 12 patients each according to SOFA score. Approval from the hospital ethical committee and informed consent from the patient/guardian were taken. Patient's heart rate, temperature, pH, ABG in both the groups on day 1, 3 and 5 were assessed. Microsoft excel was used for statistical analysis.

**Results:** The majority of patients were females, belonged to the age group of 20-40 years and were post-operative cases of perforation peritonitis. There was better control of pyrexia in CRRT group as compared to NO CRRT group. The maximum reduction of mean pulse rate in group I was 38 bpm on day 5 while in group II the maximum reduction in mean pulse rate was about 31 bpm on day 5. The changes on day 1, 3 and 5 in Bicarbonate and electrolyte levels in both groups were found insignificant.

**Conclusion:** The sepsis patients with acute kidney injury with higher SOFA who underwent CRRT showed better results than patients with Lower SOFA score Biomarkers could be helpful to define AKI but also to recognize damage to the kidney in an early stage and to evaluate preventive strategies. Moreover, functional biomarkers could be helpful in deciding when to start and stop RRT.

**Keywords:** Sepsis; Acute Kidney Injury (AKI); Continuous renal replacement therapy (CRRT).

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#### **INTRODUCTION**

Acute kidney injury (AKI), previously known as acute renal failure, indicates abrupt deterioration of function. Acute renal renal failure (ARF), classically defined as an abrupt decrease in kidney function that leads to accumulation of nitrogenous wastes such as serum creatinine (s cr) and blood urea nitrogen, is a common clinical problem with increasing incidence, serious consequences, unsatisfactory therapeutic options, and an enormous financial burden to society.<sup>1,2</sup> AKI is a common and serious complication in critically ill patients, and the development of AKI increases morbidity and mortality in these patients.<sup>3-6</sup> Sepsis is the leading cause of AKI treated with renal replacement therapy (RRT) in critically ill patients. In critically ill patients, septic shock is the cause of acute kidney injury (AKI) in more than 40% of patients in the intensive care unit (ICU). About 70% of patients with AKI require renal replacement therapy (RRT),

and in-hospital mortality is more than 60%. 7-8 Continuous renal replacement therapy (CRRT) is the established treatment modality in critically ill patients with AKI in the ICU. <sup>9</sup> Several predictors of survival in patients on CRRT have been described based on cross-sectional and retrospective studies. 10-12 It has been reported that sepsis-induced AKI is distinct from AKI in its pathophysiology without sepsis. 13-16 Therefore, sepsis-induced AKI may be distinguished from non-septic AKI in patient characteristics and clinical outcomes. Sepsis is characterized by a systemic inflammatory reaction which involves complex interactions between endothelial cells, platelets, leukocytes, coagulation system, and multiple inflammatory mediators. Sepsis may proceed to severe sepsis, septic shock and, finally, to multiple organ failure (MOF). <sup>17</sup> Severe sepsis and septic shock are major healthcare problems, affecting individuals around the world each year, killing one in four (and often more), and increasing in incidence. In addition to a mortality rate of 30 -50% in adults, sepsis carries a substantial morbidity from secondary organ failure, which occurs in over one-third of patients. The most common organ failures are respiratory and renal. Continuous renal replacement therapy (CRRT) was developed in the 1980s in an effort to provide artificial kidney support to patients who could not tolerate traditional hemodialysis. Continuous renal replacement therapy (CRRT) has been an integral part of critical care and is considered an established treatment modality for patients with AKI. 18 The aim of the study was to examine the impact in the timing of CRRT application on outcome of sepsis patients with acute kidney injury and examine the early start of CRRT within 6 hrs of maximum hemodynamic stabilization among the sepsis patients with acute kidney injury.

#### MATERIAL AND METHODS

This study included critically ill septic patients, from August 2012 to October 2013, with acute kidney injury admitted in department of anesthesiology and critical care medicine, B.R.D. Medical College & Nehru Hospital, Gorakhpur, U.P. (India). All patients were above 18 years of age. Study was conducted with due approval from

the hospital ethical committee and informed consent from the patient/guardian were taken.

All the patients were screened for predisposing factor of ARF: old age (>60 years), shock, decompensated liver cirrhosis, chronic heart failure, acute respiratory failure requiring mechanical ventilation, diabetes, septic patient, and patients receiving nephrotoxic drugs, ASA grade 3,4,5. All the patients were screened for criteria for sepsis. Patients who were excluded from study were patients with diabetes mellitus. Pregnancy, known arterial hypertension, chronic renal failure (s.cr. ≥133mmol/l), malignancy, patient who had received previous CRRT and head injury.

A total 24 patients were prospectively studied and randomly divided into two groups of 12 patients each according to SOFA score. Sepsis was divided on the basis of SOFA score and those patients with lower SOFA score were included in the No CRRT group and those with higher SOFA score in the CRRT group.

**Group I** (NO CRRT, 12patients): treated with conventional treatment (diuretics, fluid challenge along with sepsis management)

**Group II** (CRRT, 12 patients): treated with early institution of CRRT (CVVHDF) (less than 6 hrs. of maximal hemodynamic support) in addition to the conventional treatment.

#### **Statistical Analysis**

The mean and standard deviation of various observations on day 1, 3 and 5 were calculated. As per requirements Unpaired Student t test, Fisher's exact test chi-squared test (with or without Yates' correction) were applied.

#### **RESULTS**

In group I male: female ratio was found to be 1:2 and in group II the ratio was found to be 1:1. The gender distribution in both the groups was found to be insignificant (p>0.05). (Figure 1)

Mean age in group I was 33.5±14.36 yrs and in group II it was 43.08±16.23yrs. Age wise distribution of patients in both the groups was almost symmetrical. The mjority of patients belonged to the age group of 20-40 years. (Figure 2)

Figure 1: Gender Distribution of patients in two groups

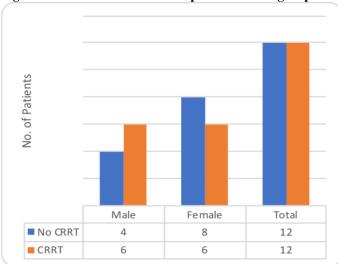
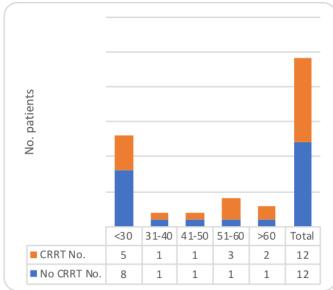


Figure 2: Age distribution of sepsis patients in two groups



Majority of the patients were post-operative cases of perforation peritonitis (33.33% in group I and 33.33% in group II) followed by APE patients with emergency LSCS in group I and obstructed labor with hysterectomy I in group II. (Table 1 and 2)

Table 1. Tomas of diagnosis in CDDT ansum

Table 1: Types of diagnosis in CRRT group			
Diagnosis	CRRT (%)		
Perforation Peritonitis	33.33		
Obstructed Inguinal Hernia	8.33		
Obstructed Labour with			
Hysterectomy	16.67		
Port partum Eclampsia with			
Pulmonary Odema	8.33		
Sigmoid Volvulus	8.33		
Uterine Perforation Followed			
D &C	8.33		
Ape with Pulmonary Odema	8.33		
Polytrauma with End			
Ileostomy	8.33		
Total	100		

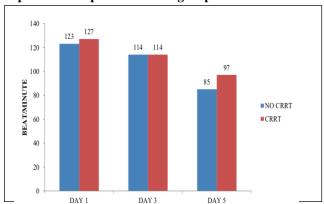
Table 2: Types of diagnosis in NO CRRT group

Diagnosis	NO CRRT (%)
Perforation Peritonitis	33.33
Acute Pulmonary Embolism (APE)	25.0
COPD with Acute Exacerbation	8.33
P/O/C of Emergency LSCS (IUD)	8.33
Puerperal Sepsis with Ascites	8.33
Delivered with PPH	8.33
P/O/C of Placenta Previa with	
Haemmohagic Shock	8.33
Total	100

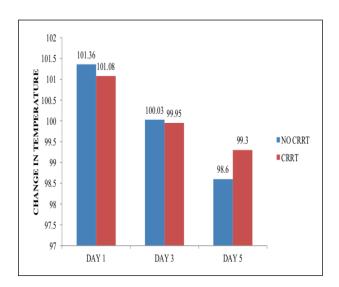
Table 3: Mean and standard deviation of Heart rate, temperature, pH and Electrolyte in study groups

temperature, pri and Electroryte in study groups						
Mode of	No CRRT			CRRT		
Treatment						
Observation	Day 1	Day 3	Day 5	Day 1	Day 3	Day 5
	(n=12)	(n=12)	(n=7)	(n=12)	(n=12)	(n=10)
Heart Rate	122.58	114	84.85	127.33	113.66	96.6
(bpm) [	<u>+</u>	<u>+</u>	±3.17	±16.02	<u>+</u>	$\pm$
mean ±s.d.]	19.48	16.79			13.94	17.91
Temperature	101.36	100.03	98.6	101.08	99.95	99.3
(°F) [ mean	$\pm$ 1.15	$\pm$ 1.21	±0.28	±1.23	$\pm$ 0.71	$\pm$ 1.36
±s.d.]						
рН	7.33	7.28	7.37	7.12	7.19	7.27
[ mean ±s.d.]	$\pm$ 0.13	$\pm$ 0.09	$\pm$ 0.01	±0.07	$\pm$ 0.13	$\pm 0.16$
Sodium	136.91	138.6	137.85	146.75	143.5	141.2
(mEq/L)	<u>+</u>	± 7.53	±3.48	± 6.85	$\pm$ 4.64	±7.53
[ mean ±s.d.]	11.82					
Potassium	5.35	4.82	3.96	5.8	5.52	4.44
(mEq/L)	$\pm$ 0.54	±0.62	±0.9	±0.29	$\pm$ 0.81	$\pm 0.86$
[ mean ±s.d.]						
Bicarbonate	17.51	19.05	24.45	13.41	16.12	19.88
(mEq/L)	$\pm 4.65$	±5.17	± 2.95	±3.0	$\pm$ 3.41	±6.23
[ mean ±s.d.]						

Figure 3 (A and B): Changes in Heart Rate and Temperatures of patients in two groups

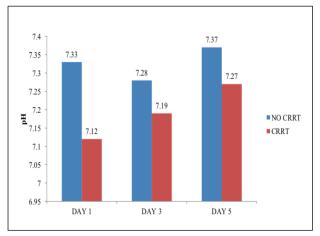


The above figure 3 (A) shows the variation of pulse rate of patients at day 1, 3 and 5 in group I and group II respectively. Mean of the pulse rates in all the patients in group I on day 1 was found to be 123 bpm. The reduction in mean pulse rate on day 3 was 9 bpm. The maximum reduction of mean pulse rate in this group was 38 bpm on day 5. Mean of the pulse rates of all patients in group II on day 1 was found to be 127 bpm. While in this group, the reduction in mean pulse rate was about 14bpm on day 3, the maximum reduction in mean pulse rate was about 31bpm on day 5.



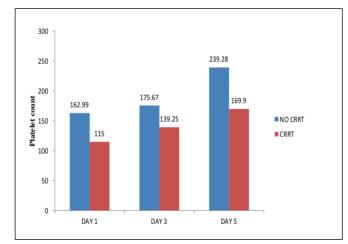
The mean temperature in NO CRRT group was  $101.36^{0}$ F,  $100.03^{0}$ F,  $98.6^{0}$ F on day 1, 3 and 5, whereas mean temperature recorded in CRRT group was  $101.08^{0}$ F,  $99.95^{0}$ F,  $99.3^{0}$ F respectively. There is better control of pyrexia in CRRT group as compared to NO CRRT group and this may be contributed cooling effect of dialyses and early control of sepsis. The observations are statistically insignificant p=0.57, 0.84 and 0.20. (Figure 3 B)

Figure 4 (A and B): pH level and Platelets count in two groups



The above figure 4 (A) shows that there is mean improvement in pH of survivals in group I and group II on day 1, 3 and 5(7.14±0.07, 7.27±0.05, 7.35±0.017 vs. 7.31±0.15, 7.36±0.05, 7.38±0.01). There is no significant change in pH of non-survival in group I and group II on day 1, 3 and 5 (7.10±0.08, 7.04±0.11, 6.9±0.05 vs.7.37±0.08, 7.18±0.04) in both the groups. But when we compare the changes in pH of two groups on day 1,

3 and 5 we see better improvement in group II (p=0.0001, 0.09 and 0.123). The metabolic improvement in survivors of group II may be partially explained by the buffering action of CVVHDF, because it was associated with a circulatory improvement, permitting a rapid reduction in vasoactive support.



Platelet count in NO CRRT and CRRT group on day 1, 3 and 5 are 162.99±98.93, 175.67±69.80, 239.28±50.88 vs.115±70.89, 139.25±67.53, 169.9±65.86. On applying unpaired t-test, these changes were statistically insignificant p=0.18, 0.21 and 0.03. (Figure 4 B)

Figure 5 (A and B): Changes in the Bicarbonate level and Potassium in two groups

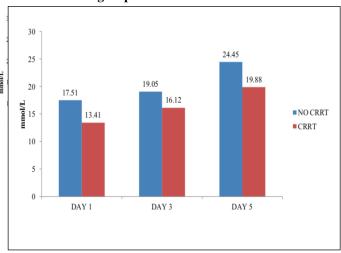


Figure 5 (A) shows Bicarbonate level in NO CRRT and CRRT group on day 1, 3 and 5 are 17.51 ± 4.65,19.05 ± 5.17, 24.45 ± 2.95 vs. 13.41 ± 3.0, 16.12 ± 3.41, and 19.88 ± 6.23. These changes are statistically insignificant p=0.018, 0.115 and 0.093.

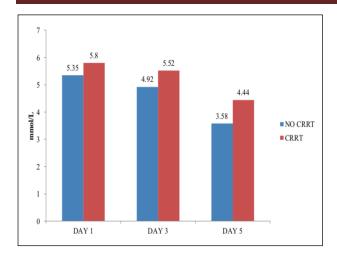
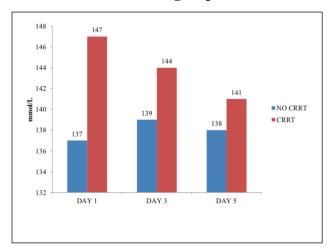


Figure 5 (B) shows the changes in electrolyte level of potassium on day 1, 3 and 5 in CRRT group were insignificant when compared with NO CRRT group (potassium p=0.018, 0.073 and 0.022).

Figure 6: Changes in the Sodium level and Serum Bilirubin in two groups



Changes in electrolyte level on day 1, 3 and 5 in CRRT group were found insignificant when compared with NO CRRT group (sodium p=0.02, 0.068 and 0.292).

# **DISCUSSION**

This study assessed the patient's heart rate, temperature, pH, ABG in both the groups on day 1, 3 and 5. Yagi et al. reviewed the records of 72 consecutive ICU patients treated with CRRT and further prospectively studied the temperature in the inlet and outlet lines for blood and dialysate of 27 other patients at various flow settings during continuous venovenous hemodialysis (CVVHD) <sup>19</sup>. Among the 72 retrospective cases, 36 episodes of hypothermia (core body temperature <35.5 degrees C) occurred and persisted for a mean of 2.6±-1.8

days. It was more frequent during venovenous than arteriovenous modalities (31 of 67 v5 of 20, respectively); no patients developed hypothermia during arteriovenous slow continuous ultrafiltration (AVSCUS), whereas 48% of the patients undergoing **CVVHD** hypothermic, became occurring earlier in the therapy course (days 2 to 4). Mean arterial pressure (MAP) tended to increase after CRRT initiation, but absolute changes were statistically insignificant. In the prospective arm, the **CVVHD** circuit temperatures were measured. Whereas no attempt was made to change body temperature, stepwise changes in blood (Qb) and dialysate flow rate (Qd) produced venous circuit temperature changes: the higher the Qb, the smaller the arteriovenous temperature differences independent of changes in Qd (P < 0.001). Also, venous circuit temperature varied directly with Qd at fixed Qb (P < 0.001). This relationship also held for temperature conversion to lost energy units per minute. Using room temperature dialysate, CRRT may significantly lower patients' core temperatures. Although the clinical significance of this effect is not clear at this point, energy loss during CVVHD may be important in hemodynamic stability or patient prognosis.

Demirjian et al.<sup>20</sup> studied 405 patients with bicarbonate based continuous hemodialysis. Serum bicarbonate and pH levels plateau after 48 hrs of CRRT. Study subjects had on average  $1.5 \pm 2.9$ days where pH was greater than 7.45, and .4 days where serum bicarbonate level was greater than 28 mEq/L, during a median of 9 days of CRRT. Daily dialysis dose was inversely associated with the number of days with a low serum bicarbonate level, but was not associated with increased frequency of an elevated pH or serum bicarbonate level. Increasing proportion of days with elevated pH or serum bicarbonate was not associated with increased mortality in multivariable analysis. They concluded that Alkalemia and alkalosis occur frequently during CRRT, butthey are not associated with increased mortality. Persistent acidosis and acidemia while on CRRT was a strong predictor of poor outcome.

This study showed that sepsis is a leading cause of AKI over time (greater than 50% of the cases). Despite the seemingly decreasing rate of mortality

from sepsis, some studies have shown that the rates of sepsis or septic shock have been increasing at an annual rate of 8 to 13%. 21,22 In this context, data have also indicated that sepsis is the main factor associated with the development of AKI, especially in the ICU.<sup>23,24</sup> A clear association has also been found between the severity of illness and the stage of AKI. 25-27 In our sample, we noted an increased APACHE II score over time concomitant with the increased incidence of D-AKI. Despite advances in the management of patients with AKI, most studies have shown persistently high mortality rates. Others have indicated a slight decrease in mortality.<sup>28</sup> Another important aspect regarding outcomes is dialysis dependence at hospital discharge and in the long-term. Some observational studies have suggested that dialysis therapies may influence the recovery of renal function after an episode of AKI. Thus, continuous therapies seem to decrease the need for dialysis compared with conventional hemodialysis. <sup>29,30</sup> In the multivariate analysis, the APACHE II score and sepsis-associated AKI in medical patients were independent risk factors related to death. Bagshaw and cols. have shown that sepsis-induced AKI occurs more frequently in medical patients with higher severity illness scores on ICU admission. Such individuals have longer hospital stays and exhibit higher mortality rates than those of patients with AKI not associated with sepsis.31

#### **CONCLUSION**

The sepsis patients with acute kidney injury with higher SOFA who underwent CRRT showed better results than patients with Lower SOFA score. Biomarkers could be helpful to define AKI but also to recognize damage to the kidney in an early stage and to evaluate preventive strategies. Moreover, functional biomarkers could be helpful in deciding when to start and stop RRT. The expanding body of research in AKI and the continued emergence of ideas for new research give us hope that better outcomes are in store for the patient of the future.

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# CLINICO-EPIDEMIOLOGICAL ASPECTS OF GALL BLADDER DISEASE PATIENTS IN NORTHERN INDIA

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#### **ABSTRACT**

**Introduction:** Gall bladder diseases are common clinical entity affecting the adult population of both sexes, and the presentation may range from flatulent dyspepsia, acute cholecystitis and its complications like perforation, peritonitis, gangrene, fistula, empyema, chronic cholecystitis and carcinoma of gall bladder. Gall stones are quite prevalent in most western countries, while no statistics are available of the overall incidence of cholelithiasis in our country. The present study was undertaken to find the epidemiological trends and the clinical aspects of gall stones disease and cancer of gall bladder in Kanpur District.

**Material & Methods:** The clinicopathological study on gall bladder disease was conducted after taking approval by Institutional Ethics Committee out on a prospective basis on 77 patients admitted in the department of Surgery, LLR and associated Hospitals with symptoms and signs suggestive of gall bladder disease. The bile was sent for culture and composition and gall bladder was sent for histopathology. The data was statistically analysis using Microsoft excel and non- probability sampling was applied.

**Results:** Out of 77 gall bladder disease cases, 57 (74.02%) were benign and 20 (25.97%) were malignant. Chronic cholecystitis (64.91%) with cholelithiasis (48%) was showing most common pattern of gall bladder diseases. Peak incidence of benign gall bladder disease was in the age group of 40-50 years and of malignant diseases was in the age group of 50-60 years. Benign and malignant gall bladder diseases were more common among females. Patients with history of 3 or more pregnancies had a higher percentage of cholelithiasis. Non-vegetarians were found to suffer more with benign (65%) and malignant (60%) gall bladder diseases. Pain in abdomen was the most common symptom encountered in all gall bladder diseases. Jaundice was more common in malignant disease. Duration of illness was less than 5 months in most patients of benign (61.4%) and malignant (70%) diseases.

**Conclusion**: The present study concludes that benign gall bladder diseases were more common than malignant gall bladder diseases. Early detection and treatment of the disease is required.

**Keywords:** Benign disease; malignant disease; gallstones; chronic cholecystitis.

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#### INTRODUCTION

Gall bladder disease are common clinical entity affecting the adult population of both sexes, and the presentation may range from flatulent dyspepsia, acute cholecystitis and its complications like perforation, peritonitis, gangrene, fistula, empyema, chronic cholecystitis etc. to carcinoma of gall bladder. Approximately 98% of patients with symptoms of gall bladder disease have gall stones.

Carcinoma gall bladder is uncommon but not rare, slightly less than 3% of all patients who are identified and explored for anticipated benign disease of the gall bladder and biliary tree have cancer of gall bladder. Carcinoma of gall bladder is now a day getting more importance because of its increasing frequency and frequent use of ultrasonography in abdominal disease. Gall bladder and bile ducts are derived from the primitive foregut

and are formed in conjunction with the liver. Gall bladder is located in the bed of liver in line with that organ's anatomic division into right and left lobes. Anatomically it is divided into four portions: Fundus, Body, Infundibulum (Hartman's Pouch) and the neck. <sup>2</sup> Gall bladder is supplied by cystic artery, a branch of the right hepatic artery, is usually given off behind the common hepatic duct. The tortuosity is known as "Caterpillar" turn or "Moynihan's" hump. Venous return is carried through small vein which enter directly into liver from gall bladder and a large cystic vein which carries blood to right portal vein. <sup>3</sup> Gall stone vary from pure cholesterol (white) through mixed, to bile salt predominant (black). 4 The major factor determines the formation of cholesterol stones. <sup>5</sup> Most of the Knowledge about gall bladder stone formation were given as triangular coordinates graph which was later modified. 6,7 Gall bladder impaired emptying promotes gall stone formation & stasis. <sup>8</sup> Infection has little importance in cholesterol stones and have role in brown pigment stones formation.<sup>9</sup> The steady increase in gall stones prevalence with advancing years is probably due to cholesterol content in bile. 10 Gall stones both of pigment & cholesterol types are reported in childhood. 11 There have been racial differences in gall stones formation. 12,13 Masai tribes of east Africa rarely develop gall stones and their bile has a low cholesterol content. <sup>14</sup> Relatives of patients with gall stones have increased frequency of gall stones irrespective of their age, weight and diet. 15 High familial prevalence of gall stone emphasized in the first-degree relatives of gall stone patients. 16 Genetic factor that may predispose a patient to cholesterol gallstone have been identified in mice and humans. <sup>17</sup> The ratio between female and male is as high as 14:1 in case of adolescents. <sup>18</sup> Little is known about the clinico-epidemiological aspects of gall bladder diseases and gall bladder cancer patients. Etiological factors that appear to be important for the development of gall bladder cancer include genetic characteristics, gall stone disease, bile composition, calcification of gall bladder, congenital biliary cysts, some infections, environmental carcinogens and drugs. Therefore was undertaken to study this study epidemiological trends and the clinical aspects of gall stones disease and cancer of gall bladder among patients in Kanpur District.

#### MATERIAL AND METHODS

The clinicopathological study on gall bladder disease was conducted out on a prospective basis on 77 patients admitted from December 2002 to May 2004 in the department of surgery, LLR and associated Hospitals with symptoms and signs suggestive of gall bladder disease. The bile was sent for culture and composition and gall bladder was sent for histopathology.

Following protocol was followed in cases suggestive of gall bladder disease.

#### **History**

Patients age, sex and religion were noted.

- (A) History of present illness with special reference to
  - o Pain in right hypochondrium
  - o Flatulent dyspepsia
  - o Fever with/without chills and rigors
  - o Jaundice
  - Weight loss and anorexia
  - o Bowel disturbance
  - o Lump
  - o Typhoid fever
- (B) History of past illness
  - Similar attacks of pain, typhoid and jaundice.
- (C) Personal history
  - o Parity
  - o Dietary history-
- (D) Family history
- (E) Examination of patient
- (F) Investigation

#### **RESULTS**

A total of 77 patients were admitted for benign and malignant diseases of gall bladder.

Table 1: Distribution of gall bladder disease

Diseases	No. of Patients	Percentage (%)
Benign	57	74.02
Malignant	20	25.97

A higher proportion of cases were of benign disease (74.02%) followed by malignant disease (25.97%). (Table 1)

Table 2: Distribution of various benign gall bladder disease (n= 57)

Diseases	No. of	Percentage
	<b>Patients</b>	(%)
Chronic Cholecystitis with	37	64.91
cholelithiasis		
Acute Cholecystitis	6	10.52
Cholecystitis with	5	8.77
cholelithiasis		
Mucocele of gall bladder	2	3.50
Empyema of gall bladder	3	5.26
Cholecystitis with	2	3.50
cholangitis		
Biliary fistula	2	3.50

Out of 57 benign cases, majority of cases were of Chronic Cholecystitis with cholelithiasis (64.91%) followed by Acute Cholecystitis (10.52%). And Cholecystitis with cholelithiasis (8.77%). (Table 2)

Figure 1: Age-wise distribution of gall bladder disease

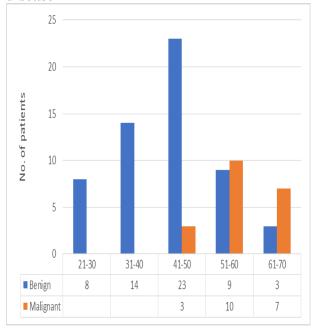
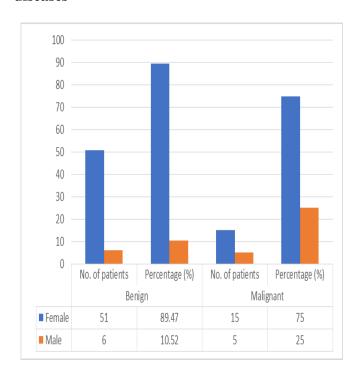


Figure 1 shows that the maximum number of benign cases were found in age-group of 41-50 years (40.3%). Majority of cases were aged up to 50 years. The total number of cases aged up to 50 years was 45 (78.94%). Among the malignant cases, maximum number of patients aged above 50 years was 17 (85%).

Figure 2: Sex-wise distribution of gall bladder diseases



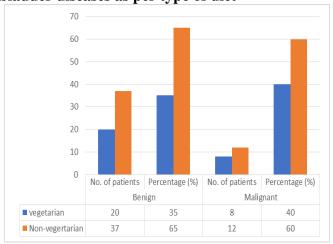
Female to male ratio in benign disease is found to be 8.5:1. Female to male ratio in malignant diseases is 3:1. Majority of cases of gall bladder diseases were females (85.71%). For benign diseases, the total number of female cases was 51 (89.47%), for malignant diseases the number of cases found was 15 (75%). (Figure 2)

Table 3: Distribution of the patients with Gall bladder diseases according to parity

No. of Births	Cholelithias is (n=47)	Percen t (%)	Carcinom a gall bladder (n=20)	Perc ent (%)
0	2	4.25	-	-
1	4	8.50	-	-
2	5	10.63	4	20
3	14	29.78	13	65
4	17	36.17	3	15
>4	5	10.63	-	-

Out of 53 cases, 47 females showed gall stones on ultrasound report. Gall stones were most frequent in females with history of 4 child births followed by those with 3 child births. Incidence of stones was less in nulliparous females. Carcinoma of gall bladder was found to be more common in females with 3 child births. (Table 3)

Figure 4: Distribution of the patients with gall bladder diseases as per type of diet



Benign disease was commoner in non-vegetarians (65%). Malignant disease was also found to be more common in non-vegetarian patients (60%). (Figure 4)

Table 4: Distribution of clinical features in gall bladder diseases

Symptoms	Ве	enign	Ma	lignant
	No. of Percentag		No. of	Percentag
	Patient	e (%)	Patient	e (%)
	S		s	
Pain in right	57	100	18	90
hypochondriu				
m				
Nausea &	49	85.96	17	85
vomiting				
Fever	9	15.78	-	-
Itching	2	3.50	7	35
Anorexia &	3	5.26	13	65
weight loss				
Urine	2	3.5	12	60
discolouration				
Stool	2	3.5	12	60
discoloration				
Past history of	45	79.94	14	70
similar attacks				
Past history of	3	5.26	8	40
jaundice				
Past history of	3	5.2	7	35
Typhoid				

The patients with symptoms of pain in abdomen (right hypochondrium) was the most common symptom of benign and malignant gall bladder diseases. Out of 57 cases of symptom of benign diseases all patients (100%) suffered with pain in abdomen. In case of malignant gall bladder diseases 18 out of 20 suffered with pain in abdomen which accounted for 90%. Nausea & vomiting were present in 49 cases (85.96%) of benign and 17 cases

(85%) of malignant diseases. Other features in benign diseases were fever (15.78%), itching (3.5%), Anorexia & weight loss (5.26%) and urine and stool discoloration (3.5%).

Distribution of same features in malignant diseases was fever & itching (35%), anorexia & weight loss (65%) and urine and stool discoloration (60%). (Table 4)

Table 5: Clinical findings in gall bladder diseases

Findings	Ве	enign	Mal	ignant
	No. of Patien	Percenta ge (%)	No. of Patien	Percenta ge (%)
	ts		ts	
Tenderness	47	82.45	16	80
(in right				
hypochondri um)				
Lump in	2	3.5	17	75
right				
hypochondri				
um				
Hepatomegal	-	-	7	35
y				
Jaundice	2	3.50	10	50
Ascites	-	-	3	15

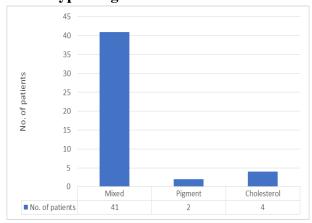
Among benign cases most common finding was tenderness in right hypochondrium (82.45%). Lump in right hypochondrium was present in 3.5% cases. In malignant cases tenderness in right hypochondrium was seen in 80% cases, lump in right hypochondrium was present in 75% cases and liver was palpable in 35% cases. Jaundice was present in 3.5% cases of benign diseases and 50% cases of malignant diseases. Ascites was present in 15% cases of malignant diseases. (Table 5)

Table 6: Duration of illness among patients with gall bladder diseases

Findings	Ве	enign	Mal	ignant
	No. of	Percenta	No. of	Percenta
	Patien	ge (%)	Patien	ge (%)
	ts		ts	
Less than 5	35	61.4	14	70
months				
tenderness				
(in right				
hypochondri				
um)				
More than 5	22	38.59	6	30
months				

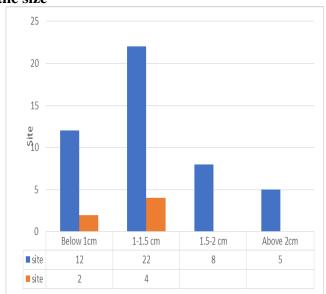
In both benign as well as malignant cases, majority of cases were having complaints for less than 5 months. In benign cases, it was in 35 cases (61.4%) and in malignant, it was found to be in 14 cases (70%). (Table 6)

Figure 5: Distribution of patients operated with different types of gall stone diseases



The macroscopic examination of the stones showed that 41 cases (87.23%) has multifaceted stones that are mixed stones, 4 cases (8.51%) were having mulberry shaped cholesterol stones and 2 cases (4.25%) had pigmented stones. (Figure 5)

Figure 6: Distribution of gall stone according to the size

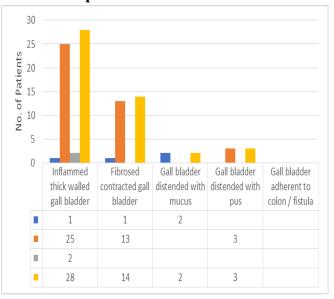


(Site represented in Blue- Gall bladder Site represented in Orange- gall bladder disease and CBD)

The majority of stones found in gall bladder were of size 1-1.5 cm followed by below 1cm and those

found in gall bladder and CBD were of size 1-1.5 cm followed by below 1cm. (Figure 6)

Figure 7: Morphology of gall bladder and gall stones of the patients



The above figure 7, suggests that the most common morphological picture was a slightly inflamed thick-walled gall bladder.

#### DISCUSSION

Gall bladder diseases are common clinical problems encountered by the clinicians in day care surgery. Of total gall bladder disease benign diseases are far more common than malignant ones. In present study, which was carried out on 77 cases, 57 were benign and 20 cases were malignant which imparts benign a percentage of 74.02% and malignant 25.97%. Benign diseases are the most common entity is chronic cholecystitis with cholelithiasis. This is the most common gall bladder pathology.<sup>5</sup> Acute cholecystitis was second commonest entity in this study, having 10.5% cases of benign disease. This imparts a bigger percentage to chronic cholecystitis with cholelithiasis than acute one. Acalculous cholecystitis was found in 2-12% of all cases of acute cholecystitis. 19 In the present study, cases were reported having 33.33% increased which is due to small sample size. Further study showed that acalculous cholecystitis is more common is males. <sup>20</sup> Fortunately, in the present study both were males. 60% cases of cholangitis were with choledocholithiasis. <sup>21</sup> In the present study, 50 % cholangitis were cases of having choledocholithiasis. Prevalence of gall stones

peaked in age group of 50-60 years. <sup>22</sup> Increased exposure of gall bladder wall which was documented. <sup>23</sup> Role of progesterone component of female hormone in gall stone was emphasized. <sup>24</sup> The range of 33 to 84 years for patients with carcinoma gall bladder was reported. <sup>25</sup> The mean age was 56 years for cancer gall bladder in a previous study <sup>26</sup> and in the present study, the mean age was of 58 years. The study reflected the same female preponderance. <sup>27</sup> Most patients with cholesterol stones (75%) were non-vegetarian and all patients with pigment stones were vegetarian. High fibre diet may prevent and low fibre diet might facilitate the formation of cholesterol gallstones. <sup>28</sup>

#### **CONCLUSION**

The present study concludes that benign gall bladder diseases were more common than malignant gall bladder diseases. Early detection and treatment of the disease is required.

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# ROLE OF HEPATIC VEIN WAVEFORM AND LIPID PROFILE AS PROGNOSTIC INDICATORS IN PATIENTS OF LIVER CIRRHOSIS

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#### **ABSTRACT**

**Introduction:** Hepatic vein waveform and serum lipid profile are useful in the diagnosis and management of liver disease. This study was undertaken to evaluate hepatic vein waveforms and serum lipid profile in patients with cirrhosis and to study prognostic value of hepatic vein waveform and lipid profile as single parameters in patients with cirrhosis.

**Material & Methods:** This study was carried out in Lokmanya Tilak Municipal Medical College, Sion, from October 2003 to November 2004 on patients of cirrhosis of liver. Seventy six patients of cirrhosis of liver who had attended gastroenterology outpatient department of the hospital were included in the study. The hepatic vein waveforms and lipid profile in patients were compared to healthy controls.

**Results:** 40 % of patients with Type 5 waveform expired over 6 months follow up. Mean Child Pugh Score in patients with Type 1 waveform was  $5.14 \pm 0.55$ , while it was  $9.8 \pm 3.63$  in Type 5 waveform. Similarly mean MELD score in type 1 hepatic Vein waveform patients was  $5.6 \pm 1.74$  while it was  $21.6 \pm 9.50$  in patients with type 5 waveform. Mean total cholesterol was significantly reduced in cases as compared to controls (132.33 vs 200 mg %).

**Conclusion:** Right hepatic vein waveform show definite alterations with development of cirrhosis. Flat waveform in right hepatic vein is a significant prognostic marker in patients with cirrhosis. Serum Lipids especially HDL, LDL and Total cholesterol reduce significantly with development and decompensation of cirrhosis but have no prognostic significance.

**Key words**: Hepatic vein waveform, lipid profile, liver cirrhosis, ultrasonography.

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#### **INTRODUCTION**

Liver cirrhosis is one of the important causes of mortality and morbidity in developing countries. Timely diagnosis of cirrhosis is necessary for early prediction of its consequences such as liver etc<sup>1</sup>. encephalopathy, variceal hemorrhage Parenchymal changes in liver cirrhosis patients echogenicity increased superficial include nodularity<sup>2</sup>. Doppler Duplex Ultrasonography (DDU) has been used in portal hypertension patients to measure portal vein flow and velocity<sup>3</sup>. Aggressive methods, in addition to spending a lot of time, are associated with life-threatening hazards. DDU is useful in distinguishing different grades of liver cirrhosis and also for predicting portal hypertension and esophageal varices as important life threatening consequences of cirrhosis<sup>4,5</sup>. Hypolipidemia is observed as independent predictor of survival in HBV-cirrhosis patients<sup>6</sup>. There is significant decrease in serum total cholesterol, LDL cholesterol, VLDL cholesterol, HDL cholesterol, and serum triglyceride level in liver cirrhosis patients belonging to Child-Pugh Class C<sup>7</sup>. Lipid profile reduction in liver cirrhosis patients is significantly associated with the Child-Pugh and MELD prognostic markers & can be used in

evaluation of liver diseases severity<sup>8,9</sup>. Isolated hypocholesterolemia can be used to assess the progression of liver disease<sup>10</sup>. Therefore aim of present study is to evaluate hepatic vein waveforms and serum lipid profile in patients with cirrhosis and to study prognostic value of hepatic vein waveform and lipid profile as single parameters in patients with cirrhosis.

#### MATERIAL AND METHODS

This study was carried out in Department of Gastroenterology, Lokmanya Municipal Medical College, Sion, Mumbai, from October 2003 to November 2004 on patients of cirrhosis of liver. Institutional Ethics Committee approved the study and informed consent was obtained from all included subjects. Seventy six patients of cirrhosis of liver who had attended gastroenterology outpatient department of the hospital were included in the study. The hepatic vein waveforms in patients were compared to those in thirty age and sex matched healthy controls undergoing ultrasonographic examination. The lipid profile results in patients were similarly compared to twenty matched controls without any liver, renal or metabolic illness.

#### **Inclusion Criteria for cases-**

- 1- Willingness to enroll in the study.
- 2- Hemodynamically stable patients of liver cirrhosis diagnosed by Clinical parameters, Biochemical parameters, Ultrasonography, Liver Biopsy etc.

# **Exclusion Criteria for cases-**

- 1- Significant Cardiac dysfunction diagnosed by Clinical Examination, Electrocardiogram, Echocardiography.
- 2- Tense Ascites
- 3- Hemodynamic Instability.
- 4- Diseases affecting Lipid Profile like uncontrolled Diabetes Mellitus or hereditary hyperlipidemia etc.
- 5- Grade III or IV hepatic encephalopathy

### **Inclusion Criteria for controls-**

- 1- Age and Sex matched
- 2- No clinical evidence of Liver, Cardiac or Respiratory illness.
- 3- Willingness to participate in the study.

#### **Exclusion Criteria for Controls-**

- 1- Presence of Liver, Cardiac, or any other major illness.
- 2- Diseases affecting Lipid Profile like uncontrolled Diabetes Mellitus or hereditary hyperlipidemia etc.

Apart from detailed clinical examination and routine biochemical tests like hemogram, complete Liver Function tests and renal function tests, patients underwent USG-doppler and 2-D echocardiography (whenever indicated). Serum Lipid profile was done in the department of biochemistry. MELD score was calculated at Mayo clinic calculator site.

#### **Ultrasound Examination**

Single examiner carried out ultrasound examination for all the cases and controls, using duplex ultrasound equipment with a probe of 3.75 MHz provided by pulsed Doppler and a color flow mapping device. Each subject was examined while in the supine position and after overnight fast. After visualization of the hepatic vein along its longitudinal axis by color flow mapping, Doppler shift signals were obtained from the middle of hepatic veins. During examination, each subject was asked to simply stop breathing in non forced expiration within 10 S to avoid modification caused by deep inspiration and Valsalva maneuver. We classified the Doppler waveform of hepatic veins into six types –

I- Triphasic waveform

II-Biphasic waveform without reversed flow

III-Decreased amplitude of phasic oscillations

IV- Flat waveform with fluttering

V- Completely flat waveform with fluttering

VI - No waveform.

#### Statistical Analysis-

Data was entered and analyzed using SPSS. Mean and standard deviation were calculated for each parameter of all three groups. Student t test and Z mean test was used to find the significant difference between two groups, and for the categorical data Chi-square test was used. P<0.05 was considered as significant for each variable.

#### **RESULTS**

Table 1: Age wise distribution of subjects

Range	Cirrhosis ( no.)	Controls ( no.)
<20 Yrs	2	1
21-40 Yrs	25	10
41-60 Yrs	38	15
>60 Yrs	11	4
Mean Age <u>+</u> SD	46.97 <u>+</u> 12.96	45.8 + 11.3
years	years	years
	(15-74)	(18-68)

Mean age of cases of cirrhosis was 46.97 + 12.96 years with range of 15-74 years. Mean age of controls was 45.8 + 11.3 years with range of 18-68 years (Table 1).

**Table 2: Hepatic Vein Waveforms in Cirrhosis** 

Hepatic	Child	Child	Child	Controls	Mortality
Vein	A	В	C		
waveform	(No.)	(No.)	(No.)		
Type 1	4	1	-	30	0
Type 2	5	5	10	-	3/20
					(15%)
Type 3	5	10	11	-	6/26
					(23%)
Type 4	3	4	12	-	5/19
					(26%)
Type 5	2	-	3	-	2/5 (40%)
Type 6	-	1	-	-	-
NS)*					

Hepatic Vein Waveforms were studied in Right hepatic veins. They were graded accordingly into six types. Hepatic Vein Waveform Type 6 was seen in only one patient with associated hepatocellular carcinoma\*, hence was not included in the study group. All 30 controls had type 1 waveforms. 40% of patients with Type 5 waveform expired over 6 months follow up, 15 % of patients with Type 2 waveform expired over 6 months while there was no expiry in patients with Type 1 waveform over 6 months follow up. On comparing flat waveform patients (Type 4 & 5) with Type 1, 2 or 3, there was significant difference in mortality between flat waveform patients (Type 4 & 5) and Type 1 waveform patients. (p<0.001) (Table 2)

Table 3: Hepatic Vein Waveforms versus Child-Pugh and MELD score

	I ugh and MEED score						
Type	No.(pt)	Age (	Child	MELD	Significance		
		yrs)	Score	Score			
Type	5	45.1 +	5.14 <u>+</u>	5.6 <u>+</u>	-		
1		12.1	0.55	1.74			
Type	20	46.97	8.75 <u>+</u>	15.75 <u>+</u>	>0.05		
2		<u>+</u>	3.17	6.81			
		12.96					
Type	26	44.97	8.84 <u>+</u>	15.04 <u>+</u>	>0.05		
3		<u>+</u>	2.075	6.611			
		10.21					
Type	19	49.7 <u>+</u>	9.21 <u>+</u>	19.052			
4		12.96	2.15	<u>+</u> 7.50	p<0.001		
Type	5	48.67	9.8 <u>+</u>	21.6 <u>+</u>			
5		<u>+</u> 13.6	3.63	9.50			

Table 3 shows that Mean Child Pugh Score in patients with Type 1 waveform was  $5.14 \pm 0.55$ , while it was  $9.8 \pm 3.63$  in Type 5 waveform. Similarly mean MELD score in type 1 hepatic Vein waveform patients was  $5.6 \pm 1.74$  while it was  $21.6 \pm 9.50$  in patients with type 5 waveform. The mean Child-Pugh and MELD scores in type 4 & 5 waveform patients were significantly more than the respective mean scores in patients with Type 1 waveforms. (p<0.001)

**Table 4: Lipid Profile in Cirrhosis** 

Serum Lipids	Cirrhosis	Controls	Significance
	(mean)	(mean) mg/dl	<b>(p)</b>
	mg/dl		
Total	132.33	200 <u>+</u> 40	P<0.001
cholesterol	<u>+</u> 44.7		
Triglycerides	91.09	100 <u>+</u> 40.6	p>0.05
	<u>+</u> 38.02		
HDL	28.24	50 <u>+</u> 10.5	P<0.001
Cholesterol	<u>+</u> 13.49		
LDL	83.82	124 <u>+</u> 32	P<0.001
Cholesterol	<u>+</u> 33.6		
VLDL	20.017	20 <u>+</u> 9.1	p>0.05
	<u>+</u> 9.24		

Serum Lipid profile was measured in all cases. Mean total cholesterol was significantly reduced in cases as compared to controls (132.33 vs 200 mg %). Mean Serum HDL Cholesterol and LDL Cholesterol were also significantly less in cases than in controls. (p<0.001) (Table 4).

Table 5: Lipid Profile among Surviving and Expired Cases

Variables	Survived	Expired	Significance
	Mean	mean	<b>(p)</b>
	(mg/dl)	(mg/dl)	
Total	134.4 <u>+</u> 48.02	124.1 <u>+</u>	>0.05
Cholesterol		27.81	
VLDL	20.5 <u>+</u> 10.0	18.2 <u>+</u> 5.45	>0.05
HDL	28.7 <u>+</u> 13.9	26.5 <u>+</u> 12.1	>0.05
LDL	86.1 <u>+</u> 34.8	75.1 <u>+</u> 27.8	>0.05
Triglycerides	92.0 <u>+</u> 38.6	87.2 <u>+</u> 36.4	>0.05

Table 5 shows that there was no significant difference between lipid profile of two categories of expired and survived cases. (p >0.05)

Table 6: Lipid Profile Versus Child-Pugh Score

Serum Lipids	Child Score		
	Correlation( r)		
Total cholesterol	-0.17 p>0.05		
Triglycerides	-0.03 p>0.05		
HDL	-0.39 p<0.05*		
LDL	-0.07 p >0.05		
VLDL	0.01 p>0.05		

Table 6 shows that there was significant correlation between HDL and Child Pugh Score. (p<0.05)\* However other Lipids did not correlate significantly with Child-Pugh Score.

Table 7: Lipid Profile among Child-Pugh Subgroups

Serum	Child	Child	Child	Contro	Significan
Lipids	A	В	C	ls	ce (p)
	(mea			mg/dl	
	n <u>+</u>				
	SD)				
	mg/d				
	l				
Total	138.5	138.4	125.4	200 <u>+</u>	P<0.001
cholesterol	7 <u>+</u>	<u>+</u>	8 <u>+</u>	40	
	52.18	48.41	38.03		
Triglycerid	81.68	100.8	90.60	100 <u>+</u>	p>0.05
es	<u>+</u>	5 <u>+</u>	<u>+</u>	40.6	
	33.40	38.18	40.02		
HDL	33.36	31.9	23.37	50	P<0.001
Cholesterol	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u> 10.5	
	14.38	13.39	14.38		
LDL	85.71	87.11	80.91	124	P<0.001
Cholesterol	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u> 32	
	36.61	35.27	31.72		
VLDL	18.91	20.91	20.14	20 <u>+</u>	p>0.05
	5 <u>+</u>	<u>+</u>	<u>±</u>	9.1	
	10.23	8.91	9.05		

The mean serum concentrations of Lipids were evaluated in different Child Subgroups and compared with concentration in the control group. There was significant reduction in serum HDL, serum total cholesterol and serum LDL cholesterol concentrations in the Child C group in comparison to their concentration in the control group (p<0.001). Other lipid concentrations showed insignificant reduction. (Table 7)

#### **DISCUSSION**

Our study found that flat (Type 4 and Type 5) waveform in right hepatic vein were associated with significantly high short term mortality (30%) as compared to Type 1 waveform in which there was no mortality (p<0.001). Mortality in Type 2 waveform patients was 15% over 6 months follow up (p>0.05) while there was 23% mortality in Type 3 waveform patients (p>0.05). Ohta et al<sup>11</sup> found 2year survival rate of 93.3 % in type 1 waveform, 76.6 % in those with type 2, 64.9 % in those with type 3, and 0% in those with type 4 waveform in right hepatic vein. We found significant difference between the mean Child Pugh score in flat (type 4 & 5) waveform and type 1 waveform (p<0.001). The difference between flat waveform and Type 2 or Type 3 waveform however was not significant. (p>0.05) Ohta et al<sup>11</sup> also found significant difference between mean Child-Pugh score in type 1 or 2 and type 4 waveform in right hepatic veins. They also studied left hepatic veins. In left hepatic veins, there was significant difference between mean Child-Pugh score in type 1, 2 or 3 and type 4 waveforms. Colli et al<sup>12</sup> studied the relationship between abnormal hepatic vein waveform and liver histology in chronic liver disease. They found correlation between degree of fibrosis waveform. Hamato N et al<sup>13</sup> studied the noninvasive comparative index (QXs ratio) of the HV Doppler waveform phases in patients with a variety of liver significant differences diseases. There were between groups of controls, chronic hepatitis and cirrhosis patients (p < 0.001). We also compared mean MELD score in type 1-waveform patients and that of type 3, type 4, and type 5 patients. There was significant difference between flat (type 4 & 5) waveform and type 1 waveform (p<0.001). Bolandi et al<sup>14</sup> considered that the underlying mechanism of the flattening change in hepatic vein waveform could be related to the amount of liver fibrosis and that the fibrosis might compress hepatic veins. Ohta et al<sup>11</sup> hypothesized that the flattening change of hepatic vein waveform may be related to change in liver compliance due to liver fibrosis and to an increase of hepatic venous blood flow per cross sectional area. Present study found reduction in the serum lipid concentrations in patients as compared to the control group. The extent of reduction was significant in Serum HDL, LDL and total Cholesterol (p<0.001). On comparing controls with patients in individual Child groups, there was significant reduction in the serum HDL, LDL and total cholesterol concentrations between controls and Child C group. (p<0.001) All lipid parameters showed negative correlation with Child's Score except VLDL; however this did reach statistical significance. Only Serum HDL showed significant correlation with Child's Score. Malaguarnera M et al <sup>15</sup>found similar reduction in the lipid parameters on grouping the patients into Child's classes as the disease progressed. Bories PN et al<sup>16</sup> found apolipoprotein A1 and high-density-lipoprotein (HDL)-cholesterol correlated with tests of liver function. Similarly Ben-Ari Z et al <sup>17</sup> also found that only Serum HDL was significantly lower in the Chronic Liver Disease (P < or = 0.05) and correlated with severity of liver disease. Other lipoprotein abnormalities in patients with chronic liver disease showed no significant correlation between any of lipid parameters and the severity of liver disease. Present study found no significant difference in the lipid profile of expired and the survived cases. Ahaneku JE et al <sup>18</sup> also found that when compared with controls, plasma total cholesterol (TC) and high density lipoprotein cholesterol (HDLC) were low in cirrhosis. They also found that plasma albumin levels showed a negative correlation with PL/TC and a positive correlation with HDL-cholesterol in cirrhosis.

#### **CONCLUSION**

Doppler Ultrasound of hepatic veins is a non-invasive and cost-effective imaging technique and now it is routinely used in evaluation of the liver in both normal and cirrhotic patients. In present study, right hepatic vein waveform show definite

alterations with development of cirrhosis. Hemodynamic changes in the liver vascularity affecting hepatic veins are correlated with based on Child Pugh score. Dyslipidemia is commonly observed in chronic liver disease. Our study concludes that decrease in lipid profile is significantly associated with the Child-Pugh and MELD prognostic markers. Therefore lipid profile can be used as a tool in evaluation of liver disease.

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# BREAST LUMPS AND ASSOCIATED FACTORS AMONG FEMALES IN DISTRICT KANPUR

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#### **ABSTRACT**

**Introduction:** Breast cancer is the most common cancer in females reported worldwide with approximately one million new cases each year as well as one of second leading cause of death among females. The present study was undertaken to identifu the causes and associated factors of breast lumps among females who attended the surgical clinic of a tertiary hospital of District Kanpur.

**Materials and Methods:** Fifty cases were evaluated at Ganesh Shankar Vidyarthi Medical College & Hospital, Kanpur, Uttar Pradesh. Female patients aged between 20-90 years with breast lumps and FNAC positive reports belonging to clinical Stage 1, Stage II and Stage III disease that were willing for surgery and other treatment modalities were included. The study was approved by Institutional Ethics Committee. The data was subjected to statistical analysis using Microsoft excel and non- probability sampling was applied.

**Results:** Mean age of the patients was 49.66 years. Majority of cases belonged to age group of 41-50 years followed by 31-40 years age group. 64% of patients had their first childbirth before 20 years. None were nulliparous. About 30% had positive family history for breast cancer. 46% were Pre-menopausal women. Upper outer quadrant was the most common site for breast cancer.

**Conclusion:** Early age of menarche has predisposition towards breast cancer. Early detection and effective management of the disease is required.

**Key words**: Breast lump, quadrant, breast cancer, FNAC

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# INTRODUCTION

Majority of females visit the clinic with the common appearance of breast lump. A breast lump may be malignant or non-malignant. Although majority of breast lumps are benign.<sup>2</sup> diagnosis of benign from malignant lesions is significant as breast cancer is the worst fear of a female presenting with a lump in the breast. Any female who demonstrates with a breast lump has to be systematically examined and inspected using the triple test. The sensitivity and specificity of clinical breast inspection is estimated to be 54% and 94% respectively depending upon the method of the examiner.<sup>3</sup> Internationally, there is growing alertness about the significant morbidity and mortality of breast lumps, particularly breast cancer. The incidence is dissimilar in different parts of the world. In the U.S.A, one out of every eight women is diagnosed with breast cancer during her life time, infiltrating ductal carcinoma is the most common variety. 4,5 On national level we need mass alertness regarding finding of early breast cancer and to foster information about the medical and socioeconomic implications of this common public health issue. The probability of breast cancer rises with age but breast cancer tends to be more aggressive when it occurs in younger people. One type of breast cancer that is especially aggressive and disproportionately occurs in younger people is inflammatory breast cancer. It is initially staged as Stage III b or Stage IV. It also is unique because it often does not present with a lump so that it often is not detected by mammography or ultrasound. It presents with the signs and symptoms of a breast infection like mastitis. Breast tissue in females is under the influence of various hormones and subjected to constant physiological variations throughout reproductive life and beyond. <sup>6,7</sup> As for death rates, they have been steadily decreasing, especially in younger women, owing to the improved treatment and early detection <sup>8</sup>; however, breast cancer in young women remains a great challenge to patients, families and health care providers. Although the diagnosis of breast cancer is much less common in women under the age of 40 years, it can have a greater impact than in older counterparts, as it tends to present at a later stage, be more aggressive and have a poorer prognosis. <sup>9,10</sup> Thus, we conducted our study in order to know the causes and associated factors of presentation of breast lumps in females who presented to the surgical clinic and compare it with studies conducted elsewhere.

# **MATERIAL AND METHODS**

The data used in the study was obtained from 50 cases that were evaluated at Ganesh Shankar Vidyarthi Medical College & Hospital, Kanpur, Uttar Pradesh, ready for further treatment and were ideal candidates for the inclusion criteria mentioned below:

#### **Inclusion Criteria**

- Female patients who were willing for surgery and other treatment modalities
- Age between 20 90 years
- All patients with breast lumps and FNAC positive reports
- Patients who belong to clinical Stage 1, Stage II and Stage III disease

#### **Exclusion Criteria**

- Pregnant women
- Patients with benign breast diseases
- Excludes all inoperable advanced breast malignancies
- Patients with inflammatory breast carcinomas
- Recurrent breast lump in a previously operated case of carcinoma breast

A detailed clinical history was elicited from all patients at the time of admission. All patients who had clinical and FNAC evidence of malignancy were worked up for treatment modalities. The history, findings and reports obtained were entered in the proforma of all patients.

All patients who were willing for mastectomy were explained about the surgery and chemoradiotherapy to be given after the procedure, the option of breast conservation surgery and the need breast reconstruction to a few patients. Various investigations were obtained for the same.

#### **Intervention:**

- Surgical intervention in the form of mastectomy depending on the stage of disease with adjuvant chemotherapy in all the selected cases.
- Neoadjuvent chemotherapy given preoperatively to selected patients while chemo-radiotherapy with hormonal therapy were given to a few cases.

#### **Procedure:**

Almost all the patients were operated under general anesthesia. Patients were given pre-op antibiotics and anti-anxiety drugs and were brought to OT. They were placed in supine position on the OT table with arm extended and a sandbag placed beneath the shoulders. A transverse elliptical incision which was about 5 cm away from the lesion and which included the nipple was marked with a marker. In few cases an oblique elliptical incision was used. Medial limit was upto lateral border of sternum and laterally it extended upto anterior axillary fold. Elevation of skin flaps were performed between the subcutaneous fat and the mammary fat. The skin flaps were held up and dissection was performed. Raising of the upper flap was done to the upper limit of the breast. This was usually 2-3 cms below the clavicle but varied from patient to patient. A good guide was the second intercostal space. Any bleeders were cauterized. The lower flap was also raised in the similar manner. The uppermost part of the breast was then elevated to and dissection was done until the fascia of the pectoralis major was visualized. A sub mammary plane of cleavage between the fascia and the breast was created. This dissection was preceded downwards. If the tumour appeared to infiltrate into the pectoralis major, then a portion of the muscle was excised with the specimen. Medial and lateral ends were ascertained and elevation of the breast was done laterally to complete its removal from the chest wall. Care was taken to identify and ligate one or two major perforating vessels passing through the second and third intercostals spaces. Identification of the lateral border of the pectoralis major was done and the axillary tail and axillary contents were cleared along this border. Latissimus dorsi was identified and axillary contents were cleared from its anterior border. Axillary clearance was then performed. A satisfactory result was achieved by preserving the pectoralis minor muscle and dissecting upto the Level II lymph nodes. Negative Suction drainage with 14 Fr Romovac suction drain was used in majority of cases. One was placed in axilla and one beneath the lower flap but both were brought out from the lower flap. Patients received antibiotics and analgesics in the post-operative period. Drains were usually removed within 72 hours. Active shoulder movements were advised. Sutures were usually removed once the wound healed, at around 7th or 8th Post-op day. Patients were then started on chemotherapy with respect to the stage of the disease.

#### **Statistical analysis:**

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean + SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data are made, Assumptions: 1) Dependent variables should be normally distributed, 2) Samples drawn from the population should be random, and Cases of the samples should be independent.

#### **RESULT**

The data used in the study was obtained from 50 cases that were evaluated at Ganesh Shankar Vidyarthi Medical College & Hospital, Kanpur, Uttar Pradesh.

**Table 1: Age distribution of patients** 

Age in years	Number	Percentage	Sen & Das Gupta Series <sup>11</sup>
21-30	5	10.0	3.33
31-40	10	20.0	23.8
41-50	17	34.0	36.9
51-60	8	16.0	25.2
61-70	6	12.0	7.61
71-80	3	6.0	3.8
81-90	1	2.0	0.0
Total	50	100.0	100.0

Mean  $\pm$  SD = 49.66  $\pm$  14.53

Table 1 depicts that the age distribution in patients studied. In which, mean age of the patients under study was 49.66 years. Majority of cases belonged to age group of 41-50 years followed by 31-40 years age group. i.e. 34.0% and 20.0% respectively. Minimum percentage of patients belongs to age group 81-90 years. The percentage of patients decreases with the increase in age.

Table 2: Associated factors among patients with breast lumps

Age of	Number	Percentage	Other study
Menarche			•
(years)			
10-11	20	40.0	=
12-13	24	48.0	=
14-15	6	12.0	=
Age at first	Number	Percentage	Mac Mohan
birth (years)			Series 12 %
17-20	32	64.0	32.9
21-25	14	28.0	27.9
26-30	4	8.0	39.2
Parity	Number	Percentage	
Parity 1	-	-	=
Parity 2	13	26.0	=
Parity 3	20	40.0	=
Parity 4	6	12.0	=
Parity 5 &	11	22.0	=
above			
Family history	Number	Percentage	Kelly et al <sup>13</sup> %
Absent	35	70.0	60.0
Present	15	30.0	40.0
Menopausal status	Number	Percentage	Raina et al series <sup>14</sup>
Pre	23	46.0	49.7
Post	27	54.0	50.3

It was seen in the study that majority of patients had menarche between 12 - 13 years. In the present series none were nulliparous, 64% of patients had their first childbirth before 20 years followed by 21-25 age group who constituted 28%. In the study, none were nulliparous, 3 children were the most common value in about 40% of the patients with 2 children at 26%. About 30% had positive family history for breast cancer while 70% did not have any history. In the present study it was noted that 46% were Pre-menopausal women while 54% were Post-menopausal women. (table 2)

Table 3: Characteristics of breast lumps among the subjects

Characteristics	Number		Percentage	Other Series
Pain/Discomfort			Tyagi et al	Regato 15 %
Absent	2 8	56. 0	66.5	88.0
Present	2 2	44. 0	33.5	12.0
Side of				
Involvement		T ==	1	T
Left	2 5	50. 0		-
Right	2 5	50. 0	-	-
Size cm3				
< 3	1 9	38. 0	-	-
3-5	1 5	30. 0	-	-
>5	1 6	32. 0	-	-
Quadrant		, v	Silverstein et al <sup>21</sup>	Sen & Das Gupta Series
С	6	12. 0	12.0	9.0
LI	5	10. 0	6.0	7.0
LO	1	2.0	10.0	11.0
UI	6	12. 0	12.0	13.0
UO	3 2	64. 0	60.0	49.0
Flexity				
Nil	3 8	76. 0	-	-
Present	1 2	24. 0	-	-

Table 3 illustrates that the characteristic of breast lumps in the patients studied. In the study, pain/Discomfort was noted in 44% of the patients. Equal incidence of cancer was noted in both the right and left breasts. 38% of cases had lump size of < 3cm<sup>2</sup>. 64% of the patients had the lump in the upper and outer quadrant. 76% of the cases did not have any fixity to the skin or underlying structures.

Table 4: Characteristics of nipple among the subjects

Retraction	Number	Percenta	Other study
		ge	Tyagi et al
			<b>%</b> (16)
Absent	26	52.0	89.2
Present	24	48.0	10.8
Discharge			
Absent	34	68.0	89.2
Present	16	32.0	10.8

Table 4 shows that the characteristic of nipple in the patients studied. Nipple retraction was noted in 48% of the cases while nipple discharge was noted in only 32% of the cases studied. While nipple retraction was absent in 52% of the cases while nipple discharge was absent in 68% of the cases studied. Tyagi et al shows only 10.8% nipple retraction andnipple discharge.

#### **DISCUSSION**

All women are at risk for breast cancer, regardless of hereditary factors. In fact, 85 to 90 percent of breast cancer incidences cannot be explained by inherited genetic predisposition. Other known risk factors and personal characteristics include personal or family history of breast cancer, high breast tissue density, earlier onset of menstruation (12 years or younger), late menopause (55 years or older), late first-term pregnancy (30 years or older), no children or no breast-feeding, early or recent use of oral contraceptives, more than four years use of hormone replacement therapy, postmenopausal obesity, alcohol consumption, exposures to secondhand cigarette smoke and exposure to ionizing radiation.<sup>17</sup> In the present study, peak incidence of breast cancer was 34% between 41-50 years of age suggested by Indian data Sen et al 11 had also published similar findings and 36.9 had in the same age group, which is similar to present study. Early age of menarche has always been associated with risk of breast cancer. 88% of the patients in the present study had menarche between 10-13 years of age. Peeter et al 18 suggested that women with menarche of age 10 or 11 years showed 2.2 times higher risk for breast cancer compared to women who had their first menstrual period at 12 years and above. In the present study 64% patients had first birth at 17-20 years of age. MacMohan et al 12 reported equal incidence in all age group. Mukherjee et al<sup>19</sup> suggested that except for parity no other reproductive factor plays any role in the incidence of breast cancer. In the present study none were nulliparous, 3 children were the most common followed by 2 children. No relationship between parity and incidence of breast cancer could be drawn. In present study 30% of the patients had relevant family history for breast cancer that was diagnosed of breast cancer in our hospital. Kelly et al 13 showed family history positivity in 40% of

cases, although it was noted that such patients had usually an earlier stage of presentation they were aware or the disease. In present study, it was noted that 46% were in the pre-menopausal age group and 54% in the post- menopausal age group, in other studios Raina et al 14 had 49.7% or patients in the pre-menopausal age group while the rest was postmenopausal. Pain and discomfort was noted in about 44% of the population while breast lump was seen in the 100% of the cases. Tyagi et al 16 suggested 33.5% of the cases presented with pain and discomfort while 12% was suggested by Regato <sup>15</sup>. Loprinzi et al <sup>20</sup> suggested that 60% of their cases had the tumour in the upper outer quadrant while Sen and Dasgupta 11 found 49% of the cases in the same quadrant. About 64% of the cases in the present study had the tumour in the upper outer quadrant. Tyagi et al 16 reported that 10.8% of their cases had nipple retraction. In the present study 48% of the cases had nipple retraction while 52% cases had no evidence of retraction.

#### **CONCLUSION**

Early detection and effective management of the disease is required.

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