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Atypical Presentation of a Rare Hematological Malignancy in the Lung

By Jolsana Augustine, Rajesh V, Mobin Paul & Latha Abraham

Abstract- We report the case of a young healthy gentleman who initially presented with an acute bronchitis like syndrome, which rapidly evolved into sustained pyrexia with lung infiltrate. He subsequently had a rapid downhill course with progressive pulmonary and systemic involvement due to an uncommon aggressive hematological malignancy. We would like to highlight the fact that focal airspace opacity in the lung has many infectious and non-infectious differentials and accurate diagnosis holds the key.

Keywords: NK cell leukemia, fungal pneumonia in healthy person, fever of unknown origin.

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Atypical Presentation of a Rare Hematological Malignancy in the Lung

Jolsana Augustine α, Rajesh V σ, Mobin Paul ρ & Latha Abraham α

Abstract- We report the case of a young healthy gentleman who initially presented with an acute bronchitis like syndrome. which rapidly evolved into sustained pyrexia with lung infiltrate. He subsequently had a rapid downhill course with progressive pulmonary and systemic involvement due to an uncommon aggressive hematological malignancy. We would like to highlight the fact that focal airspace opacity in the lung has many infectious and non-infectious differentials and accurate diagnosis holds the key.

Keywords: NK cell leukemia, fungal pneumonia in healthy person, fever of unknown origin.

Introduction

ggressive natural killer cell leukemia (ANKL) is a distinctly rare neoplastic disease of mature natural killer (NK) cells classified as a separate entity in the World Health Organization 2016 classification. [1] The earliest report dates back to 1990 [2] and literature search reveals less than 200 cases reported in the literature. [3] ANKL has a distinct geographic distribution with most reported cases occurring in Asians. The entity commonly affects young to middle aged adults, and is almost always associated with Epstein Barr virus (EBV) infection. ANKL has a rapidly fatal clinical course with a median survival of around 1 month in one of the largest series published. [4] Due to lack of unified diagnostic criteria a combined approach combining clinical features, imaging modalities and pathological studies (with relevant markers) is helpful in diagnosis. Herein we describe a patient who presented to the respiratory OPD mimicking a usual viral lower respiratory infection, but turned out to be lodging this grave disease with a catastrophic course.

CASE SUMMARY II.

A 34 year old gentleman, driver by occupation presented to Pulmonary Medicine outpatient department (OPD) with a history of cough for 10 days. He denied history of any medical illness. He experienced mild left sided pleuritic chest pain for 5 days. There was

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no history of associated fever, loss of appetite, loss of weight.

On examination, he had expiratory wheeze. Rest of the physical evaluation was unrewarding. Chest at initial presentation was unremarkable. A diagnosis of viral upper respiratory infection was entertained and he was given a course of bronchodilators with oral steroids. He was advised to follow up in OPD if symptoms persisted for more than two weeks. He presented again in the OPD after three weeks with worsening cough and chest pain. He had lost three kg of body weight in last three weeks and started experiencing poor appetite. His total leucocyte count was 5.2x10 9/l; C -reactive protein was 1.5 mg/dl. His renal, liver and thyroid function tests were within normal limits. Chest-X ray was repeated which showed subtle left lower zone infiltrate. Computed tomography (CT) chest demonstrated focal area of air space infiltrates in left lower lobe abutting pleura with surrounding ground glass opacities consistent with Halo Sign [Figure 1a and b].

Bronchoscopy was performed; lavage was retrieved from left lower lobe segments and was subjected to appropriate microbial tests. BAL cultures grew aspergillus fumigatus in significant titres. Mantoux test was non-reactive. BAL galactomannan was positive. Subsequently he was started on oral antifungals (Voriconozole) and was treated on an outpatient basis as he was stable. He was advised close monitoring.

He presented in emergency department within a week with new onset high grade fever and further three kg weight loss. Chest-x ray showed an increase in left lower zone alveolar shadows. His blood and urine cultures were negative. He was admitted and treated with intravenous voriconozole and broad spectrum antibiotics. Despite five days of antibiotics and antifungals, he had persistent high grade fever. This prompted a detailed evaluation for persistent fever. His serology for Brucella, Chlamydia, PCR throat swab for influenza A (H1N1) were negative. Serology for viral markers (HIV, HBsAG, HCV) were nonreactive. Serum ACE, ANCA and ANA by IFA were negative. Serum LDH and ferritin levels were normal. His repeat CT chest revealed worsening left lower lobe consolidation. CT paranasal sinus was normal. Amphotericin was added to his antifungal regime. A transesophageal echocardiography revealed evidence of no cardiac vegetations.

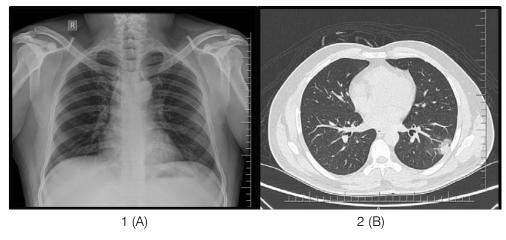


Figure 1: Chest radiograph showing subtle left lower zone infiltrate. Computed tomography image showing Halo sign

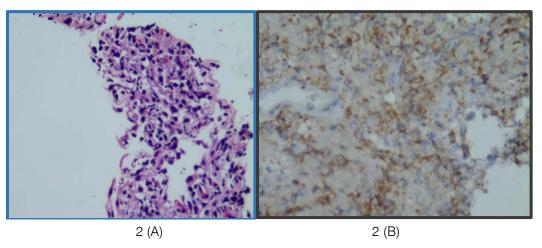


Figure 2: A, B Lung biopsy: H&E, 400 x shows interstitial infiltration by atypical lymphoid cells Lung biopsy: Immunohistochemistry, 1000 x shows CD 56 positive lymphoid cells

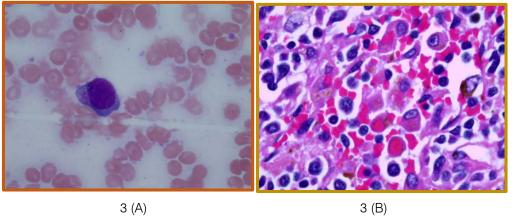


Figure 3: A, B Bone marrow aspirate: Leishman, 1000 x shows atypical large cells with blastoid morphology and cytoplasmic granulation Lymph node biopsy: H&E, 1000 x shows haemophagocytic histiocytes

CT abdomen revealed mild splenomegaly and portocaval lymph node (LN). Leucopenia and thrombocytopenia started to set in at this juncture and (BM), positron emission tomography (PET CT) and abdominal lymph node biopsy were suggested. PET CT

he started to get hypoxic. A multidisciplinary discussion was conducted with Internal Medicine and infectious disease experts. Biopsy of lung lesion, bone marrow demonstrated F-18 fluorodeoxy glucose (FDG) avid large portocaval LN, non FDGavid small axillary nodes, demonstrated F-18 fluorodeoxy glucose (FDG) avid large portocaval LN, non FDGavid small axillary nodes, bilateral cervical, aortocaval LN: heterogenously avid humeral and femoral marrow and left lower lobe lung lesion. CT guided biopsy of left lower lobe lesion, surgical biopsy of caval lymph node and bone marrow studies were undertaken. Since he started developing altered mentation, a cerebrospinal fluid (CSF) study was also performed which showed lymphocytic pleocytosis with few atypical cells, cultures were unrewarding.

Quantitative EBV titres were 1,888,738 copies/ml in his blood sample. BM showed normal karyotype.BM immunophenotypic (IHC) and flow cytometry (Table 1) profile was suggestive of NK /Large granular lymphocytic leukemia (NK/LGL) [Figure 3a]. The same was correlated with histopathology and IHC of lung [Figure 2a, b] and lymph node [Figure 3b].CSF immunophenotyping was done to rule out any invasion but showed no definite CD3 negative / CD8 positive population in CSF.

Table 1: Flow cytometry profile

Marker	Percentage of gated population	
T cell m	arkers	
CD2	99	
CD3	17	
CD4	06	
CD5	38	
CD7	47	
CD8	64	
B cell m	arkers	
CD10	00	
CD19	02	
CD19+CD5	00	
CD20	08	
CD23	00	
NK cell n	narkers	
CD56	43	
CD16	16	
Myeloid r	narkers	
CD13	03	
CD33	00	
CD64	00	
CD117	00	
Other m	arkers	
CD45	100	
CD34	00	
CD38	82	
CD57	31	
CD11B	13	
TCR gamma -delta	00	
CD11C	66	
HLA DR	83	
FMC 7	05	
cCD3	88	
Note – Test performed on 4 colors BD F through Lyse wash preparation	ACS using single page analysis	

Based on all aforementioned results, a diagnosis of aggressive NK cell Leukemia was arrived at. He was initiated on L-asparaginase based chemotherapy regimen. He developed febrile

neutropenia and succumbed to his illness. The total disease course from initial presentation to death spanned less than eight weeks.

Discussion III.

Natural killer (NK) cells constitute the third lymphoid lineage other than T-cell and B-cell lineages. Both NK-cells and T-cells arise from a common lymphoid progenitor, thus justifying their grouping under a common heading in the WHO classification of neoplasms. [5]

killer Aggressive natural cell leukemia/lymphoma (ANKL) is a rare and highly aggressive neoplasm. Men and women are equally affected and the disease usually manifests in the third or fourth decades. The neoplastic cells are almost invariably infected with Epstein Barr virus (EBV). Blood EBV antibody titres and EBV DNA loads are very high.

Pulmonary involvement in ANKC leukemia is rare with only a few cases reported so far. [6] The significant majority of case reports have been from South East Asian countries. Patients present with fever, cough, dyspnea, and other symptoms with no antibiotic response. Radiologically, the lesions can present as focal alveolar infiltrates (consolidation), or distinct lesions (pulmonary nodules and masses). As the lesions are angiocentric and angioinvasive, bleeding is often observed and the halo sign may be seen as in our case.

The diagnosis of ANKL neoplasms is often difficult. It requires high index of clinical suspicion and a multidisciplinary approach. A dedicated and detailed pathological evaluation based on morphological, immunophenotypic and molecular studies mandatory. [4] Most cases of ANKL were diagnosed from the presence of NK neoplastic cells in peripheral blood. bone marrow or tissue. NK cells appear as large granular lymphocytes with pale cytoplasm and abundant azurophilic granules. Peripheral blood cytopenias may be found in about 10-15% of cases of NK cell lymphomas and are mainly due to active hemophagocytosis in the marrow. The hemophagocytic cells are activated reticuloendothelial cells and the presence of these cells by itself does not equate to marrow infiltration. NK T cell lymphoma and ANKL tumor cells nearly always express CD2 and less often CD7 and CD8. Most useful and frequently positive marker is CD56. CD 16 is positive in about 75% of ANKL, which helps to differentiate it from extranodal NK T cell lymphoma.[7] Practical approach to a successful diagnosis is based on suggestive IHC and EBVencoded small RNA (EBER) detection in a BM biopsy.

Even with the best of treatment chances of survival in aggressive NK cell leukemias is dismal. L-asparaginase based regimens (SMILE protocoldexamethasone, methotrexate, ifosfamide, L-asparaginase, etoposide) followed by consolidation HSCT showed relatively prolonged survival than antracycline regimes in some cases.[8] In a large series involving L-asparaginase based chemotherapy followed HSCT, two patients are alive and in clinical remission

after 2 years. [9] Rapidly growing lung mass and positive EBER herald a poor prognosis. The recurrence rate is very high and most cases succumb in weeks.

IV. Conclusion

Aggressive natural killer cell leukemia is a rare malignancy caused by proliferation of mature natural killer cells. Pulmonary involvement in this rare neoplasm is exceedingly rare. In the absence of uniform diagnostic criteria, the diagnosis rests on morphological tests and immunological sequencing of the pathological specimen of an involved site. Response to therapy is dismal and median survival time spans a few weeks only. Awareness about the entity and multidisciplinary assessment is crucial for diagnosis and prognostication.

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Development of an Obstetric Anesthesia Chart using the Digital Pen and Paper in a Low Resource Setting: A Prospective Interventional Study

By Chimhundu-Sithole T, Shumbairerwa Samson & Madzimbamuto Farai

Abstract- Background: The anesthetic chart is an essential part of the medical record, with the electronic chart being the gold standard. The digital pen and paper system (DPPS) may be a potential bridge between expensive electronic data systems and traditional pen and paper, especially in low-resource settings. The aims of this study were to revise current anesthesia charts for the obstetric population and determine whether use of the digital pen and paper system would lead to improved documentation.

Methods: The study was conducted at two large obstetric units in Zimbabwe. Retrospective audit of obstetric anaesthesia chart completeness using ANZCA PS06 scoring system was carried out prior to the study. The study design was prospective interventional study. A sample of 432 anaesthesia charts including 216 charts prior to DPPS introduction and 216 charts after DPPS introduction.

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Results: Chart completion rate was 47.5% in the old charts but increased to 65% in the new DPPS. This implied an improvement of 17.5% in chart completion rate. However, DPPS documentation had higher effects in postoperative documentation (mean difference 20%) as compared to preoperative documentation (mean difference 10%). The new DPPS however had marginal effects on intra operative documentation.

Conclusion: A well-structured obstetric anesthetic chart improved the quantity of documentation. The digital pen and paper system showed potential value as a data-collection tool in low resource setting.

I. Background

he anaesthetic chart is an essential part of the medical record.¹ The volume of data which may be collected has greatly increased, making the ageold paper record inadequate.^{2,3,4} In Zimbabwe, anaesthetic data is collected manually with one generic

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chart for all subspecialties. The Division of Anaesthesia provides anaesthesia service in Parirenvatwa Group of Hospitals (PGH) and Harare Central Hospital (HCH), two tertiary level hospitals of 1000 beds each with high volume obstetric work of between 300-500 Caesarean sections performed monthly. In obstetric anaesthesia, data is increasingly becoming an important factor in improving maternal outcomes. Safe practice and accurate information management surroundina Caesarean section has a meaningful role to play in improving maternal mortality.5,6

Current Anaesthesia Information Management Systems (AIMS) make electronic charts more complete with accurate data collection.^{7,8} There is currently a strong move supporting automated anaesthesia records to facilitate "Big Data" research.9 However despite these advantages, AIMS implementation has met with resistance from policy makers due to its expense, the steep learning curve and cumber some equipment. 10,11 Pen and paper remains the most cost-effective, efficient and easy way of acquiring data in low-resource settings. Going fully digital in this context will have to be a gradual patchwork as departments build up electronic capabilities and prepare clinicians. A compromise is therefore required to improve efficiency of data capturing, while allowing institutions to transition towards AIMS. Digital pen and paper system (DPPS) may provide a low-cost approach to automating paper based processes without disturbing the simplicity of using ordinary pen and paper. 12,13 However, there is a paucity of published research on the use of the DPPS in anaesthesia, especially in obstetrics, with a few published studies identifying its potential use in clinical practice. 15, 16-21 Overall, few studies have assessed the adequacy of anaesthetic record-keeping, with some illustrating that documentation is generally inadequate7, 21,22.

In Zimbabwe, the anesthesia chart has undergone little change over a period of more than twenty years. A revised digital chart could improve data capturing and retrieval. This article reports on the process by which a new obstetric anaesthetic chart was designed for two teaching hospitals in Zimbabwe.

a) Aims

The aims of this study were to revise current anaesthesia charts for obstetric use and to determine whether introduction of the new chart with use of the DPPS would lead to superior data quality and quantity. The hypothesis was that peri-anaesthetic documentation in the obstetric population would be superior with the use of the new chart and DPPS.

b) Digital pen and paper technology

Digital paper is ordinary printer paper which has a pattern of microscopic dots printed on it by a laser

printer. The digital pen utilizes the dot pattern to decipher its location on the page. The pen's built-in infrared camera records the coordinates of the handwritten strokes during writing. The charts are kept in the pen's memory until they are routed to remote servers. Routing happens by putting the digital pen in a cradle fastened to a network-connected Personal Computer (PC) or via a Bluetooth-enabled mobile communication device. The handwriting is then changed to digital text and an image of the handwritten form immediately becomes available. Figure 1 shows the basic components of a digital pen and paper system.

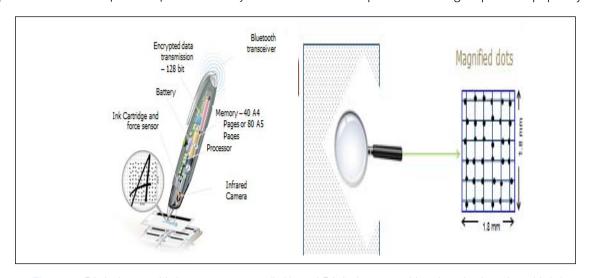


Figure 1: Digital pen with its components (left) and Digital paper with printed microdots (right)

H. **Methods**

a) Study Design

This study was prospective interventional study involving new DPPS charts and old manual charts.

b) Sample Size and Sampling Procedure

A study by Kylie-Ellen et al (1) found that traditional old charts had ANZCA compliance score of 81.6% while electronic data capture had compliance of

88.6% with a mean difference of 7.1% in comparison with handwritten records. To test the efficacy of the DPPS, a non-inferiority hypothesis was assumed that DPPS would lead to non-inferior data quality and quantity of the obstetric anesthesia chart as compared to manual documentation. Therefore the sample size used in this study was given by non-inferiority formula (2) as shown below:

$$n = \frac{\left(p_1(1-p_1) + p_2(1-p_2)\right) \times (Z_{1-\beta} + Z_{\alpha/2})^2}{(p_1-p_2)^2}$$

Where n = sample size required

 p_1 = DPPSS compliance with ANZCA (88.6%)

 p_2 = Hands written manual documentation compliance with ANZCA (81.6%)

 Z_{β} = Desired power (0.84 for 80% adopted for this study)

 $Z\alpha_{/2}$ = Desired level of statistical significance. (1.96 for 95% adopted for this study)

$$n = \frac{\left(0.886(1\,-\,0.886)\,+\,0.816(1\,-\,0.816)\right)\,\times\,\left(0.84\,+\,1.96\right)^2}{\left(0.886\,-\,0.816\right)^2} = 391.6\,\approx 392\,records$$

However, the researcher sampled 432 records (216 record for old charts and 216 records in new charts using DPPS) inclusive of 10% attrition rate.

c) Data Collection Procedure

Data was collected from anaesthetic charts, that is, the new digital charts on one arm and the old charts as the other arm. Since only one pen was available at

each hospital for the study patients were recruited in this manner: from 0800-1400hrs patients were recruited consecutively for each theatre and then from 1400hrs patients were recruited into those using the new and old charts on alternate days.

Members of staff in two departments were trained via demonstrations on use of the new sheet and pen. For this study, the Live Pen™ 1 pen (Anoto DP-201: Sweden supplied by Xcallibre, Durban, South Africa) was used (Figure 2). This was commercially acquired independently and Xcallibre were not involved in the study. A one-week pilot period was used to familiarize staff and address technical glitches. During the study, the researcher was available for troubleshooting and there were information booklets in each theatre at all times. XCallibre's cloud system provided back-up and technical support in case of system failure.



Figure 2: The digital pen with cap off switching it on

The new system was tested alongside the old charts for a month based on the ANZCA scoring system (Table 1). The sheets were assessed for completeness using a scoring system (Table 1) based on the Australian and New Zealand College of Anaesthetists (ANZCA) PS06 Anaesthesia recommendations and a tool developed by Elhalawani.4 This was also combined

with the ASA House of Delegates Statement on the documentation of anaesthesia care.²⁴ Phase I results were used to further adapt the tool for the study. The scoring system rated charts from 0 to 40. A score of zero was given to a blank chart, and 40 were given for a form 100% complete.

Table I: Scoring System for determining form completion

Anesthetic Documentation	Data field	Requirement	Maximum score
Pre-operative Encounter	Patient's name, hospital number, gender, weight	Each to be documented in both the pre-op and intra-op document	4
Liteodritei	Date	On pre-op and intra-op encounters	1
	Name of anesthetic providers	On pre-op and intra-op encounters	1
	and signature		
	Procedure	Brief description on pre-op and intra-op	2
		encounters	
	Medical status	ASA grading	1
	Medications and allergy	On pre-op assessment	1
	Previous anesthesia	List and complications (or none)	1
	Airway, dentition and GORD	Airway: Mallampati score, thyromental	3
	(Gastro-oesophageal reflux disease)	distance Dentition: any loose, false or broken teeth	1
	Premedication	If appropriate	1
	Anesthetic plan	Brief description	1
	Risks	Brief description	1
	Consent	Including for regional anesthesia	1
	Fasting	Fasting instructions	1
Intra-operative	Anesthetic machine check	Full details (general and regional)	1
Encounter	Anesthetic technique	Time and dose of administration	
	Drugs administered	Degree of difficulty, grade view, Size and type	1
	Airway	Breathing systems, flows and mode of	1
	B	ventilation	2
	Breathing system	List details (s.s. siss and site of Osmanla	
		List details (e.g. size and site of Central	1
	Monitoring method	venous catheter Intra-arterial line,) Site, size of IV access. Type and volume of	
	I Wormoning method	fluid	1
		Must be documented	'
	Vascular access and IVT	st 25 350diffortion	1
		Timing and doses	-

	Significant blood loss		1
	Vitals recorded in full		4
	Drugs administered and	Full details	1
	Antibiotics		
	Level of block		1
	Regional anesthesia		2
	documentation		
Post-operative	Post-op recovery analgesia	Pain protocols when appropriate	1
Encounter	Oxygen therapy	Where appropriate	1
	Post-op ward analgesia	Documentation on either operative record or medication chart	1
	Post-op fluid and transfusion orders	To cover 24 hours	1
	PONV (post-op nausea and vomiting) protocol	Where appropriate	1

d) Ethical Consideration

Ethics approval for the study was granted by the Harare Central Hospital (HCH) ethics committees [(HCH Ethics Committee and Joint Research Ethics Committee JREC/Ref #14/46]. Since records were uploaded onto standard Android platform, data was encrypted to protect patient identity. Only the researcher and two consultant anaesthetists had password-protected access to the files for editing and data cleaning. The database was backed up by XCallibre's cloud based system.

e) Data Analysis

Data was analyzed using Stata Version 11. Descriptive statistics such as means and standard deviation was used to describe the completeness

scores in the two types of charts. Mann Whitney U and Friedman tests were used to compare completeness scores. Findings were presented at 95% confidence interval using graphs.

III. RESULTS

a) Anaesthetic Documentation Completeness

An audit in the anaesthetic records indicated that in all cases, postoperative records had the highest level of completeness while intraoperative records had the least documentation completeness. There was significant variation in level of completeness between preoperative, intraoperative and postoperative documentation (Friedman test: $x^2 = 194.6$, degrees of freedom = 2, p-value = 0.000).

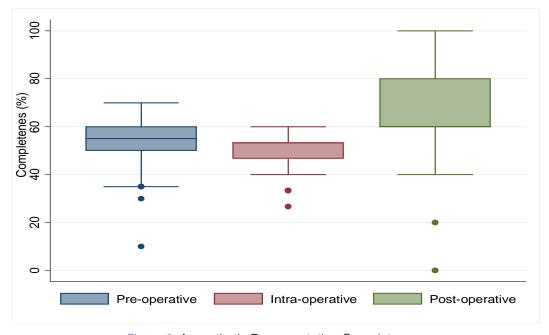


Figure 3: Anaesthetic Documentation Completeness

b) Preoperative Completeness

As shown in the figure below the median preoperative completeness of the old charts was 50%

while the median preoperative completeness of the DPPS charts was 60%. None of the charts had a preoperative completeness of more than 70%. However,

it was found that on average DPPS charts had significantly (Mann Whitney U test: Z = -8.845, p-value = 0.000) higher preoperative completeness

as compared to the old charts. This showed that the new DPPS system enhanced preoperative documentation by 10%.

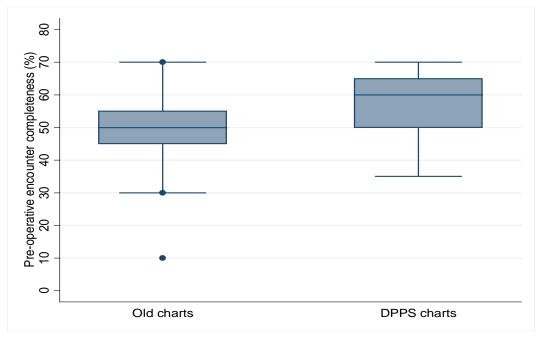


Figure 4: Preoperative Completeness

c) Intraoperative Completeness

As shown in the figure below the median intraoperative completeness for both old charts and DPPS charts was 53%. None of the charts had a completeness of more than 60%. The intraoperative

completeness in DPPS charts however was significantly (Mann Whitney U test: Z=-4.325, p-value = 0.000) higher than old charts. This showed that DPPS marginally contributed to enhancement in intraoperative documentation.

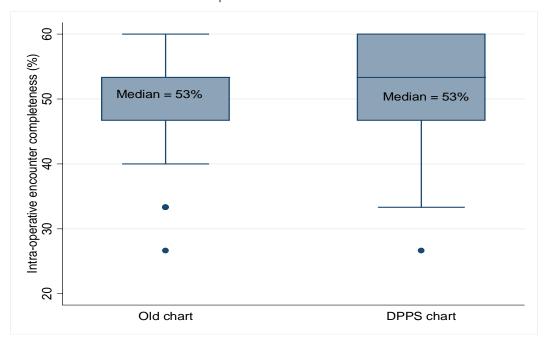


Figure 5: Intraoperative Completeness

d) Postoperative Completeness

As shown in the figure below the median postoperative completeness of the old charts was 60%

while the median preoperative completeness of the DPPS charts was 80%. Postoperative completeness of the old charts had wider variation as compared to DPPS

charts. Furthermore it was found that on average DPPS charts had significantly (Mann Whitney U test: Z = -8.049, p-value = 0.000) higher postoperative completeness as compared to the old charts. This showed that the new DPPS system enhanced postoperative documentation by 20%.

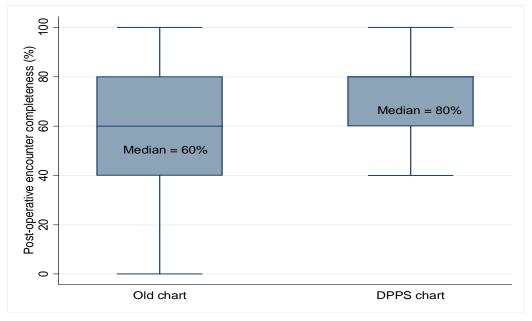


Figure 6: Postoperative Completeness

General Completeness

To assess the general completeness scores for intraoperative preoperative, and postoperative completeness were added and converted to percentages. As shown in the figure below the general median completeness of the old charts was 47.5% while the general median completeness of the DPPS charts was 65%. None of the charts had a completeness of more than 70%. In addition, it was found that on average DPPS charts had significantly (Mann Whitney U test: Z = -11.07, p-value = 0.000) higher general completeness as compared to the old charts. This showed that generally the new DPPS system enhanced anaesthetic documentation by 17.5%.

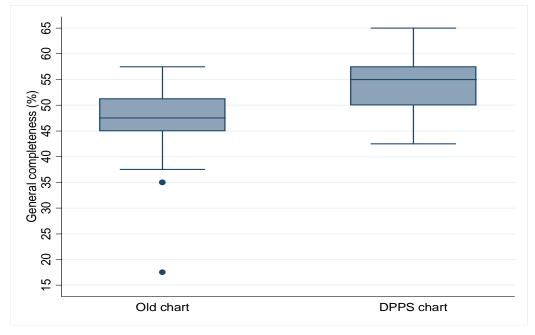


Figure 7: General Completeness

IV. DISCUSSION

Recommendations anaesthetic state documentation should be 100% complete in all aspects.4,26 Improved documentation has associated with well-designed peri-anaesthesia charts, training emphasizing the value of documentation. electronic data capture and departmental monitoring of the quality of record-keeping.^{27, 28}A new obstetric chart was designed with the hope that improved structure would boost the documentation practices. In the early phases of the study, the researcher held a training lecture on best practices in record-keeping using the new chart and DPPS. Although the principal aim was to improve format of the chart to raise documentation standards, the researcher inadvertently taught on the importance of enumerating events. Teaching was done during training on DPPS use. This may explain the generally refined documentation practices during the study.

This study found that prior to the introduction of DPPS, preoperative completion averaged 50% and intraoperative completion was 53% while postoperative completion was 60%. Other studies have demonstrated pre-operative record completion of 26.8%.²³ and a South African study had 78.1% of anaesthetic charts without a pre-operative record. 22,23 Mato also showed record completion was only 52% across disciplines including orthopedics, obstetrics, ear nose and throat and maxillofacial surgery.² On assessing record keeping during Caesarean section, Varma showed only 6% of charts were completely filled, whilst our initial audit fared at 0%.38 Olateju et al's pre-intervention audit showed 56.12% completeness for obstetric regional anesthesia documentation. 27,29 Completeness of chart documentation is therefore clearly a major problem, particularly during the pre-operative phase.

introduction After of DPPS, average documentation increased from 47.5% in the old charts to 65% using the new DPPS chart. This indicated that the mean difference between the two documentation styles was 17.5%. The new DPPS documentation had higher effects in postoperative documentation (mean difference 20%) as compared to preoperative documentation (mean difference 10%). The new DPPS however had marginal effects on intra-operative documentation. Therefore, it was concluded that the new DPPS was superior in documenting preoperative and postoperative procedures.

This study supports the hypothesis that anaesthetic documentation in the obstetric population would be superior with the use of the new chart and a DPPS. However, there were emerging problems that may need further evaluation at a later stage such as the data needing further verification and the quality of the pen-hand recognition. During the study form verification and correction was only done on 10 randomly selected

forms. Although the DPPS may be a potential bridge technology, it probably does not fully address the issues surrounding hand-recognition and the additional time required for data verification and cleaning. This will need further validation at a later stage in our unit. Dykes also showed similar potential issues of the DPPS when it was employed in 3 units at varied stages of implementing an electronic medical record.³³

V. Recommendations

To further approach the gold standard 100% documentation, we would recommend periodic departmental education on the importance of enumerating events during the manual-to-digital transition.

VI. LIMITATIONS

The study was conducted at teaching hospitals which may not necessarily depict practices at other hospitals. We assumed that users are equally capable and so individual skill would not affect documentation. Junior members of staff enter the department on a rotational basis. The study was conducted during randomly selected months without taking rotations into consideration.

VII. Conclusion

Data capture in the operating room takes many forms.³⁴ we developed an obstetric anesthetic chart using the DPPS in a low-resource setting. A digital charting tool improved data collection in terms of quantity although the quality was not fully evaluated. The DPPS showed some potential value in a low-resource setting especially with regards to degree of chart completion and facilitation of big data amongst others.

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Declaration

The authors declare that they haveno competing interests. Xcallibre is an independent company from which the study DPPS was sought commercially. The company had no involvement or financial interest in the study. All authors cited above had contributions in the conception, study design, data acquisition, analysis and development of this manuscript. The datasets used and analyzed for this study are available upon reasonable request with permission from JREC and the Ministry of Health.

List of Abbreviations

AIMS Anesthesia Information Management System ASA American Society of Anesthesiologists

- CI Confidence Interval CS Caesarean Section
- **DPPS** Digital Pen and Paper System
- FGD Focus Group Discussion **HCH** Harare Central Hospital
- **JREC** Joint Research Ethics Committee Parirenyatwa General Hospital PGH

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To Study the Maintenance of Ventilators at a Tertiary Care Teaching Hospital in North India

By Dr. Ravinder Ahlawat, Dr. Amit Lathwal, Dr. Kanika Jain & Dr. Sidhartha Satpathy

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Methodology: All the ventilators installed by a single firm at AIIMS were studied. A total of 179 ventilators supplied and installed in various inpatient areas across the hospital were studied. It was a retrospective descriptive study. Equipment related data was abstracted from the various service reports collected and compiled from the vendor and the nursing counters.

Keywords: breakdown maintenance, preventive maintenance, critical equipments, medical equipments.

GJMR-K Classification: NI MC Code: WX 218



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To Study the Maintenance of Ventilators at a Tertiary Care Teaching Hospital in North India

Dr. Ravinder Ahlawat ^α, Dr. Amit Lathwal ^σ, Dr. Kanika Jain ^ρ & Dr. Sidhartha Satpathy ^ω

Abstract- Background: Maintenance is a core function of biomedical engineering and is essential for the optimum functioning of equipment. This study was undertaken with the objective to determine whether the current maintenance practices are effective in reducing equipment breakdown and increasing the life of critical equipments such as ventilators.

Methodology: All the ventilators installed by a single firm at AllMS were studied. A total of 179 ventilators supplied and installed in various inpatient areas across the hospital were studied. It was a retrospective descriptive study. Equipment related data was abstracted from the various service reports collected and compiled from the vendor and the nursing counters. This data was used to explore the reasons and frequencies of breakdown in addition to highlighting the gap in the existing process.

Results: A total of 692 maintenance visits were undertaken for 179 ventilators of 5 different modal over a period of 27 months by 6 BME. Mean maintenance visits varied from 2.6 visits for the model E to a high of 4.5 visits for model A. Out of all the visits, 88.36% were for Breakdown Maintenance and 11.64 % were for Preventive Maintenance. Downtime ranged from 0 to 55 days with an average of 2.60 days / ventilator per year. Role of Preventive maintenance (PM) was found to be negligible in the efficient maintenance programme of ventilators. 2.8 spares and 1.6 spares were replaced per equipment when the equipment was under warranty or under CMC and 3.2 spares were replaced when the equipment was neither under warranty nor under CMC.

Conclusion: The findings of the study should enable researchers in future to formulate an effective equipment maintenance policy for the hospital.

Keywords: breakdown maintenance, preventive maintenance, critical equipments, medical equipments.

I. Introduction

n the current scenario of rapidly evolving health care, modern medical technologies have been instrumental in creating an environment wherein despite failure of vital organs; life can be sustained with the help of advanced, sophisticated equipment's like dialysers, ventilators, heart/lung machine etc. Medical Devices are health technologies that are not medicines, vaccines

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or clinical procedures but are used in diagnosis, prevention, treatment and detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.(1) Chapman et al has categorized equipment into three types namely electric, electronic and mechanical instrumentation based on the branch of engineering possessing the skills to maintain these equipment.(2)

Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment.(3) Moreover, inadequately maintained medical equipment creates an unacceptable high risk of patient injury. All these equipments account for a major part of any hospital project cost along with hospital furniture biomedical equipment accounting for nearly 50 percent of the cost. As per the study in a Canadian hospital 15-20 medical equipment are required per bed at a capital cost of 200- 4,00,000 \$. (4). Hence, it is imperative to ensure maximum utilization of the equipment with minimum downtime.

What constitutes appropriate maintenance and how to plan for medical equipment maintenance has been discussed and debated for many years without reaching any consensus.(3, 5 -13) Ministry of Health and Family Welfare (MOHFW) has classified Maintenance into two types namely Corrective Maintenance and Planned Preventive Maintenance. (3) Some authors have also classified maintenance into inspection, preventive maintenance (PM) and corrective maintenance. (3, 14, 15)

(PM) is a mix of two procedures: Safety testing (ST) and Performance Verification (PV). Planned Maintenance is a mix of Scheduled maintenance including cleaning and/or decontamination, Performance verification including calibration and Safety testing. Predictive maintenance which is a new emerging concept is a forecasting technique to determine the rate of failure of certain types of replaceable components like batteries, valves, etc.

Primary purpose of any (PM) program is to provide assurance that the facility's critical devices are functioning properly and safely at the time of their need (3, 14). M Kalaf et al has stated that it is crucial not only to improve the life of the equipment but primarily to improve patient care. (15)

For an effective maintenance program, it is imperative to develop a Monitored equipment maintenance program and the devices that should be

included in this program are either those critical devices that can cause injury if they do not function properly or those which are maintenance sensitive, i.e. they have significant potential to function improperly if they are not provided with an adequate level of "Preventive Maintenance". (14)

Appropriate maintenance intervals also play a very crucial role in determining the effectiveness of equipment maintenance. One school of thought advocates that manufacturer recommended maintenance intervals should be followed, whereas another school of thought advocates that criticality and usage should be the factors which should determine the frequency of maintenance. Ventilators being used 24 hours a day will require frequent visits than ventilators being used once in a while. [2, 4, 16 - 17] It is important to determine how the risk of adverse consequences might vary with different maintenance types and frequencies which are further determined by the number and nature of the devices non-durable parts in order to ensure their timely restoration before they can have a significant adverse effect on the functioning of the device. (14)

The choice of approaches (in house by the hospital, contact outsourcing and contact with the manufacturer) for maintenance depends upon the complexity of the equipment.(3) For specialized and advanced equipment like PET scan, MRI, it is no costeffective to develop in house services at hospital. The manufacturer shall provide maintenance services through a combination of on-call services and a (PM) contract, negotiated at the time of the purchase. Maintenance Outsourcing is concept which is in its nascent stage of development and evolution. Hence, a cafeteria approach, with a mixture of all is widely adopted for the BME maintenance and is adopted at the Healthcare organization under study. A number of authors have deliberated on the pros and cons of Maintenance Outsourcing. [18, 19, 20, 4]

The study was undertaken with the following objectives:

- To study the process of maintenance of ventilators by the vendor and to further assess the effectiveness of the existing process of maintenance
- To determine whether the current maintenance practices are effective in reducing equipment breakdown and increasing the life of critical equipments such as ventilators at a 2500 bedded tertiary care teaching autonomous healthcare organization.

The study further aimed at streamlining the current Equipment maintenance programme being followed in the Institute.

II. METHODOLOGY

The study is a retrospective descriptive study. The study was carried out in an autonomous tertiary

healthcare institute over a period of six months (December 2014 to May 2015). All the 179 ventilators serviced in the institute by a single supplier, over a period of 27 months (January 2013 to March 2015) were included in the study. The reliability of the data was established by cross checking 89 reports collected from the company with the reports available with the Sister In charges of wards responsible for maintaining the ventilators.

The data for the study was obtained from the service reports and it was compiled to help determine the parameters to measure effectiveness of maintenance. These under mentioned parameters were identified by Review of literature so as to reach a decisive conclusion.

- Down Time (in percent): The period of time the machine is not available for production or use due to maintenance or breakdown. [27]= (No. of hours equipment was out of service/total available time)* 100
- 2. Breakdown Maintenance (BM) response time. (have we calculated it)
- 3. *Mean Time to Repair:* Average of all repair time (The time between the start and finish of repair)
- 4. Periodic Preventive Maintenance(PPM) completion rates: The completion rate is percentage of procedures completed = (Number of PPM completed/Number of PPM schedule)*100
- 5. Periodic Preventive Maintenance (PPM) Yield: It is the percent of scheduled PPM procedures performed where problems were found that affected equipment operation or safety = (Number of WO in which problems identified/PPM scheduled)*100
- 6. Percentage of Biomedical engineer (BME) time spent on the maintenance of one ventilator was calculated as recommended by % BME time spent on maintenance = 100% * [Time spent on inspection, incoming testing, PM, and corrective maintenance] / [2,080 hours * number of technicians] (21)

Unstructured Interviews were conducted with the BME responsible for maintaining these equipments in the Institute as well as with other engineers from the industry to further understand the reasons of breakdowns and to understand the financial implications of these maintenance programmes. The rates of the spare parts were collected from market with the help of a private company working in the field of providing biomedical engineering solution to the hospitals. Help was sought from various BME on a number of occasions for their expert opinion and guidance. Data was entered using Microsoft Excel and Data was analyzed using SPSS Version 20.0. Cross tabulations were done to determine the significance of the visits with the nature and frequency of breakdown.

Conflict of Interest: None

Limitation: The retrospective nature of the study was a limitation to the study as some of the service reports collected from the company and the inpatient wards were not complete in all respects.

III. Observations/ Results

The maintenance of ventilators is outsourced to the manufacturer in the hospital. In each of the visit undertaken for the maintenance, a data sheet containing all essential details related to equipment maintenance was filled by the BME.

It was observed that a total of 692 maintenance visits were undertaken for 179 ventilators over a period of 27 months by 6 BME. These 179 ventilators were of 5 different models and have been installed over a period of 14 years (18-12-2000 to 29-09-2014). Due to lack of documentation, the installation dates of 19 ventilators could not be determined.

Amongst these maximum numbers of ventilators were of Model A (48%) and minimum number of ventilators belonged to model B (5%). The number of maintenance visits in relation to each these 5 models have been depicted in Table No.1. The number of Maintenance visits per equipment per year was taken as dependent factor and its relation with 5 different model of the ventilator was studied. It was observed that the mean visits varied from 2.6 visits for the model E to a high of 4.5 visits for model A. This was found to be statistically significant on applying ANOVA with a p value of 0.00.

a) Outcome of the Maintenance Visits

Out of the total maintenance visits undertaken by the BME, 88.36% were for Breakdown Maintenance and 11.64 % were for Preventive Maintenance.

In 71.50 % visits the defect was corrected during the visit and the equipment was made functional, whereas in 23.56% visits defect could not be corrected and in the remaining 4.77% visits, the outcome could not be defined due to ambiguity in the language of the in service reports. Out of all the (PM) visits, 39% were within the warranty period and 16% were during the CMC/ AMC period. This implies that during the initial years of purchase that is during the warranty period, the manufacturer provides better (PM) as compared to its later years.

The outcomes of each of these visits were assessed in correlation to the BME attending the call using ANOVA. The p- Value was found 0.000, indicating that the outcomes have a significant correlation with the knowledge, skill and training of BME attending the call.(Table 2)Hence, this draws attention to the fact that hospitals need to frame guidelines about the skill sets of manpower that will be deployed for providing maintenance of ventilator.

Frequency of the breakdown and life cycle of the equipment: The analysis of the breakdown frequency reveals that there are two peaks in the breakdown of the equipment, one during initial period varying from 0-12 months and the other during 80-90 months as can be seen in Figure 1. The later peak can be attributed to the age of the equipment whereas the initial peak could be due to lack of training to operate the new model / new type of ventilator. Thus the findings conclude that with advancement of the technology the learning curve for the equipment is slow and the duration for training This observation demonstrates increases. importance of proper induction of the new equipment with the staff. These finding are in consonance with the World Health Organization report on Medical Devices: Managing the mismatch (August 2010) where it has been described that increasing complexity of medical has important bearings technology consequences for training and outcome for care.

b) Downtime Period and Response Time

On calculating the downtime of the ventilators, it was observed that the downtime ranged from 0 to 55 days with an average of 2.60 days / ventilator per year. Out of the 612 Breakdown calls, data on response time of the engineers was available for 528 breakdown visits and out of these 528 visits, 488 visits were attended on the same day with a cumulative delay of 467 days. Such prompt response time and low downtime was possible due to the stationing of two full time BME at the hospital.

c) Effective Preventive Maintenance

As per the guidelines laid down by the hospital, (PM) has to be done quarterly. Total number of expected Preventive Maintenances during the study period was computed by taking the date of installation and four (PM) yearly. The expected (PM) visits was calculated (for date of installation before 01-01-2013 it was 9 and for the equipment installed after that the no. of completed month till 31-03-2015 were divided by 3 and decimals being neglected.) to be 686 during the study period whereas there were only 80 (11.67%) preventive maintenance. Which is a far cry from the expected numbers. Despite negligible preventive maintenance, it was observed that the downtime per equipment was well within the acceptable limit of 5%. It can then be inferred that that the role of (PM) was negligible in the efficient maintenance programme of ventilators being studied. This indicates that in the current scenario where hospitals are increasingly and microprocessor software equipment which possesses the ability to detect and display errors on a real time basis. The need of the hour is to move away from the conventional method of (PM) and instead create an in-house team trained to perform and analyze the self tests and coordinate with BME of the manufacturer. Thus, there is also a need to revisit (PM) as per the maintenance schedule recommended by the manufacturer.

d) Yield of PM

Preventive Maintenance Yield is the percent of (PM) visits where problems were found that affected equipment operation or safety = (No. of PM visits in which problem identified/(PM) visits)*100

Yield was identified as an important indicator by Ridgway M et al. it is stated that when a device is tested at a particular interval, the number of completed tests (usually expressed as a percentage) that are found to be outside the acceptable performance limit is defined as the "yield" at that particular interval and this performance deterioration is a result of the failure of small components.

In the 80 (PM) visits, 10 Spares were changed during 9 (PM) visits and none were changed during the remaining 71 visits. Due to the absence of any other indicator, to determine the effectiveness of preventive maintenance, Yield was used as a proxy and was calculated as 11.25%. However, it is felt that more studies are required to determine the importance of (PM) in correlation to yield for Critical equipments.

e) Man-Hours Spent to Maintain the Ventilator

There were only 664 working days in the study period, during which a total of 692 visits were done which translates into 1.07 visits per day. Amongst these visits the detail of man-hours utilized for the maintenance of ventilators was available for 457 visits and was found to be 523 hours and 45 minutes ranging from 10 minutes to 5 hours 15 minutes with a mean of 1 Hour 8 minutes man hours.

On calculating the percentage of time the BME spent on repair and maintenance using the following formula:

Repair time of BME utilized for one repair * mean number of repair done per day / the total available working hour of BME = 68 min (time to attend one visit) * 1.07 (no of visits per day) *100/ 60 min * 8hrs = 72.76 *100/ 480= 15.15 %

It was observed that only 15.15 % of the available time of the BME was being spent on the maintenance. The above findings indicate that if the time is optimally utilized by the personnel engaged in carrying out maintenance related tasks, they could effectively undertake many more PM related activities of ventilators in the available time.

f) Replacement of Spare in Relation to Maintenance Contract

Out of 692 visits, 488 spares were changed in 418 visits. On calculating the number of spares replaced per equipment during the study period, it was observed that 2.73 spares were replaced per equipment. It was also observed the spares were more likely to be changed when the equipment was out of warranty. On

further probing, it was observed that 2.8 spares and 1.6 spares were replaced per equipment when the equipment was under warranty or under CMC and 3.2 spares were replaced when the equipment was neither under warranty nor under CMC.

Amongst all the commonly replaced spares, the expiratory sensor was the most commonly replaced spare (80 times) followed by the oxygen cell (69 times), and expiratory valve (22) and these 3 spares accounted for 35.33 % of all the spares replaced during the study period. This indicates that it is imperative for hospitals to identify such spares at the time of procurement so that a mechanism could be devised to ensure that these spares are readily available and this will help in keeping the equipment downtime to a minimum. Identification of such spares will also help the organization to negotiate their cost with the vendor at the time of procurement which will thus be instrumental in reducing costs of maintenance.

g) Human Factor in Relation to Maintenance of Equipment

One of the potentially important factors responsible for the quality of maintenance is the attitude, knowledge and skill of the manpower engaged for providing these services. ANOVA was applied to determine the difference in quality of maintenance between different BME. The factors taken to conclude the quality of maintenance were time taken and breakdown. Amongst these time taken by the BME to attend one call was found to be statistically significant .Although Post Hoc test indicate a statistically significant difference (indirect indicator of the ability of the BME), the real difference was in fact just 20 min.

This implies that is the attitude, knowledge and skill of the manpower engaged for providing maintenance services are important and further research is required to identify the importance of each of these factors individually.

IV. CONCLUSION

In this paper the authors have attempted to gain an insight into the existing system of Maintenance of ventilators. The following conclusions can be drawn from the study:

- The knowledge, skill and training of BME attending the call have an impact on the outcome of the visit. Hence, it make it imperative for healthcare organizations to define and frame guidelines regarding the skill sets of manpower that will be deployed for providing maintenance of ventilator.
- Breakdown frequency of the equipment can be attributed to the age of the equipment and lack of training to operate the new model / new type of ventilator which further draws attention to the fact that with advancement of the technology the

- learning curve for the equipment is slow and the duration for training increases.
- 3. With evolving technology, most of our equipments are either software driven or microprocessor driven which possess the ability to detect and display errors on a real time basis. The need of the hour is to move away from the conventional method of PM and instead create an in-house team trained to perform and analyze the self tests and coordinate with BME of the manufacturer on real time basis.
- Need to redesign the existing (PM) programme as per the maintenance schedule recommended by the manufacturer.
- 5. Time being spent on maintenance was sub optimal, which points towards the fact that if the time is optimally utilized by the personnel engaged in carrying out maintenance related tasks, they could effectively undertake many more (PM) related activities of ventilators in the available time.
- 6. It was found that there were a few common spares that were being replaced time and again making it imperative for hospitals to identify such spares at the time of procurement. So that a mechanism could be devised to ensure that these spares are readily available and this will help in keeping the equipment downtime to a minimum. Identification of such spares will also help the organization to negotiate their cost with the vendor at the time of procurement which will thus be instrumental in reducing costs of maintenance.

The most significant finding of this study is the need for further research in the field of maintenance of medical devices especially in terms of the (PM) Yield and Human factors which influence the maintenance strategies adopted by the organization. Further, attention needs to be drawn to the fact that costs incurred in the maintenance of such equipments needs to be looked into so as to enable one to draw more factual conclusions and design a cost effective and efficient equipment maintenance programmes.

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Conditional Cash Transfer Programme and Newborn Care in an under-Served Community

By Subhashchandra Daga & Anushree Borhade

Abstract- Purpose: To study the feasibility of conditional cash transfer (CCT) programmes for neonatal referral services.

Methods: This prospective observational study has been conducted at a referral hospital in a rural area over five months. The newborns were referred by the primary health centre (PHC), located 5 km from the referral centre, and 50 km from the district headquarters. The PHC area has 38 villages with a total population of 60,000. Forty percent of people are tribal, and 30% are below the poverty line. Approximately 20% of the PHC area is very remote, and the terrain is hilly. The subjects of the study were 30 consecutive high-risk newborns referred from the designated PHC area.

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Results: Of the 30 high-risk newborns admitted, 22 were transferred in utero and eight after birth; three (10%) expired. The disbursement of INR 140,000.00 (USD 2000) in funds from the ZP was smooth.

Conclusion: It is feasible for a private facility to extend neonatal referral services in rural areas with CCT in place.

I. Introduction

illennium Development Goal 4 (MDG 4), a twothirds reduction in under-5 child mortality between 1990 and 2015, has not been realized since neonatal deaths, which account for 44% of the world's under-5 mortality (1), have not declined substantially. Over half of neonatal deaths globally occur in preterm babies (2). The availability and accessibility of neonatal referral services need to be enhanced to improve the care of preterm babies to reduce under-5 mortality. The estimates suggest that the interventions at a health facility can reduce neonatal mortality by 23-50% in different settings (3). Community hospitals and district hospitals appear to be appropriate to deliver these level Il newborn care services. A study that assessed the functioning of such centres concluded that although it is feasible to establish these technically intensive and expensive services, their maintenance is challenging (4).

Curative care in some countries such as India may be highly skewed towards the private sector. The private providers extend more than 80% of outpatient care and nearly 60% of inpatient care (5). Involving such providers in newborn care is essential for

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the spread of services. A low-income individual may find them unaffordable. However, the conditional cash transfer (CCT) scheme may be helpful in such a situation. CCT may extend this benefit to the deprived individuals without delay or intermediation and with transparency (6). CCT provides monetary transfers to households on the condition that they comply with some pre-defined requirements. More people can avail the neonatal referral services with the involvement of the private sector.

This study shows how a referral centre, a local district council and a primary health centre (PHC) in a remote area came together to carry out a CCT programme as a pilot project.

II. METHODS

a) Design and setting

The NICU of the Maharashtra Institute of Medical Education and Research (MIMER) and General Hospital (GH), Talegaon Dabhade, a rural medical college, located 45 km away from the city of Pune conducted this prospective observational study (1/7/2013-30/11/2013). GH is a private sector organization. The GH is a designated centre for newborn referral services under the Sharada Gram Arogya Yojana (SGAY) of which, safe motherhood and child survival are the important components. The Zilla Parishad (ZP) of Pune, a district council, the GH and the PHC, Kamshet, jointly implemented the programme.

b) Participants

The present study pertains to the care of highrisk newborns from the Kamshet PHC area born at PHC headquarters, at the GH or home. The distance between PHC headquarters and GH, and the district headquarters is 5 km and 50 km respectively. The PHC area has 38 villages and a total population of approximately 60,000, of which 40% is tribal, and 30% is below the poverty line. Around 20% of the PHC area is extra-remote and has mountainous terrain. It is difficult to reach the PHC headquarters, particularly in the rainy season, from these areas. The farthest village is 25 km from the PHC headquarters. Two general duty medical officers, seven auxiliary nurse midwives (ANMs) and two health assistants (HAs), the supervisors provide the medical care. Forty accredited social health activists (ASHAs), who are pay-for-performance workers, facilitate the programme. The PHC headquarters

witnesses 25-30 deliveries every month. The labour room of the PHC aims to stabilize a baby before transfer to the first referral unit. This programme emphasizes that the baby must reach the FRU within an hour of birth. The Styrofoam box [Beardsell India] is useful as a transport incubator (7). Each ASHA has one Styrofoam box to be used for this purpose. Most often, the PHC vehicle is available for transportation.

c) Interventions

i. Newborn care

The NICU serves as the FRU for nearby PHCs and private maternity homes. Warmth, feeding, and antibiotic and oxygen administration receive primary attention. Circulatory support is extended in form of inotrope and pulmonary vasodilator administration. The established protocols, revised over time, following monthly death audits guide the management. As a routine, complete blood counts are performed at the time of admission. In case of respiratory distress, a chest X-ray is obtained. A portable X-ray machine is available for this purpose. Continuous positive airway pressure (CPAP) is delivered by a "homemade," inexpensive (USD 2.5), and easy-to-use version of the CPAP delivery system (8, 9), when indicated. Blood gas surfactant administration, analysis, mechanical ventilation, and mechanized CPAP delivery units are not available. At best, the centre may be called a level 2+ neonatal unit. The mechanical ventilation facilities are available at Pune. For an average bed-occupancy of 13 babies, two staff nurses are on duty round-the-clock. One junior and one senior resident are present per 8-hour shift, supervised by three consultants. All doctors are responsible for pediatric outpatient and inpatient The consultants are also involved undergraduate and postgraduate teaching.

ii. The CCT

The management of MIMER & GH and the ZP administration arrived at a subsidized price structure though discussions. A system of benefit transfer, cashless to the families, was outlined. The ZP pays the charges for maternal and baby care to the GH through the PHC. The training of ASHAs ensured an early transfer, directly to the NICU rather than to the emergency rooms to avoid delays in management. The programme also stresses that admission formalities must be easy for parents and should not burden the ASHAs.

d) Outcome variables studied

The clinical profile of the babies, including outcome (survival), ease of money transfer and difficulties encountered in the study, if any, were noted. The survival rate for these babies was targeted to be equivalent to the existing survival rate in the NICU.

The study conformed to the Helsinki Declaration and to local legislation. The ethics committee of MIMER $\,$

Medical College and Hospital granted permission to conduct the study.

III. RESULTS

There were 32 admissions to the NICU during the study period. Of these, three (10%) expired (table). Eight (26.8%) babies were very low birth weight (VLBW). The birth weights ranged from 850 to 3300 g. eighteen (60%) babies were born preterm. The gestation ranged from 27-41 weeks among the admissions. The distribution of referrals was as follows: in utero (32), and after birth (8). Of the latter, 6 delivered at the PHC headquarters, and 2 at home. All the transfers, except one, reached the GH within an hour of birth. Birth asphyxia and respiratory distress respectively were noted in 5 (16.7%) and 23 (76.7%) babies. Of the three babies who expired, 2 were extremely low birth weight (ELBW) babies with severe respiratory distress. One baby, 1300 g at birth, with no asphyxia or respiratory distress died unexpectedly on day 8; a suspected sudden infant death syndrome. Five babies required second-/third-generation antibiotics, which were not available under the programme and had to be purchased by the parents. The GH received a total sum of INR 140,000 (one hundred forty thousand) for the care of these 30 babies, which was an average of INR 4660 (approximately USD 76) per baby. Overall, the was smooth. Second-generation cash transfer antibiotics were not available under the programme. Two babies required tertiary care, but the parents could not afford it.

IV. Discussion

Both arms of the programme, effective newborn care, and hassle-free CCT, were feasible at a modest expense. The survival among these babies was in line with earlier reports from our centre (10). In the absence of CCT these babies may not have presented to GH for referral care. The expenditure for the ZP was "modest." Importantly, our study offers an option for the community to choose between public and private facilities newborn care depending for convenience. The availability of second line of antibiotics and access to tertiary care may have been desirable additions.

The present study is also an example of a public-private partnership (PPP) with CCT in which access to newborn care at a private health facility is negotiated in advance. CCT, by its immediate and direct impact, may offer some parity in the accessibility of neonatal referral services in the public and private sectors. Well-designed CCT may complement essential public health services. There is consistent evidence that some CCT programmes have facilitated significant improvements in nutrition and increased utilization of health and education services (11). CCT has also played

a role in supporting care and treatment for people living with HIV and AIDS. In a systematic review of studies on CCT that report maternal and newborn health outcomes, including studies from 8 countries, it was noted that the CCT programmes have increased the uptake of maternal and neonatal health services such as antenatal visits, skilled attendance at birth, delivery in a health facility, and tetanus toxoid vaccination for mothers. Unfortunately, health agencies have remained relatively passive observers of CCT schemes rather than active participants in their design, implementation, and evaluation, possibly because most CCT schemes are "owned," intellectually and operationally, by economists working outside the health sector (12).

CCT also stimulates demand for health services and must be complemented by the supply side, such as strengthening health services to provide high-quality health care at a reasonable cost in programme areas. CCT is not an alternative to improvements in primary services. Thus, the expansion of capacity to deliver level II care at the community hospital level may be the top priority.

To conclude, it is feasible to enhance referral neonatal services in rural areas by involving private medical facilities through a public-private partnership. The real test lies in the ability of such a programme to function well under different conditions and in a larger population and to address a broader range of challenges.

What is known?

Under-served communities may not be able to access newborn referral care in the private sector, even when no other options are available to them.

What does this study add?

Conditional cash transfer may make it possible for under-served communities to receive services at private health facilities.

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Table 1: Frequency distribution of variables

Variable	Frequency	%
Place of birth		
Inborn	22	73.3
Out born	8	26.7
Birth weight (g)		
Up to 1000	02	6.7
1000-1500	06	20
1510-2500	12	40
More than 2500	10	33.3
Gestational age (weeks)		
Up to 28	05	16.7
29-34	05	16.7
35-37	08	26.7
More than 37	12	40
Sex		
Male	14	46.7
Female	16	53.3
Mode of delivery		
Vaginal	20	66.7
C-section C-section	10	33.3
Liquor		
Clear	15	50
Meconium-stained	15	50
Birth asphyxia		
Yes	05	16.7
No	25	83.3
Respiratory distress		
Yes	23	76.7
No	07	23.3
Outcome		
Discharged	27	90
Expired	3	10
Hospital stay		
Up to 7 days	04	13.3
More than 7 days	26	86.7



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Unusal Presentation of Metastasis from a Renal Cell Carcinoma- A Case Report with Review of Literature

By Dr. Meenakshi Suri & Dr. Shalini Trivedi

Abstract- Renal cell carcinoma (RCC) is the most frequent urological malignancy in adults and has a male preponderance. It accounts for approximately 3% of adult malignancies and 90%–95% of neoplasms arising from the kidney. Metastases have been reported to develop 17 or more years after the primary lesion is removed¹. Most cases invade peri-nephric fat & regional lymph nodes. Invasion of the renal vein was a common finding but nowadays seen in < 10% of cases. Most common distant sites are lungs & skeleton, also seen in the adrenal gland, liver, skin, soft tissues, CNS & ovary.²

This is the case of a 57- year-old male, who presented with a left abdominal wall mass, which was proven to be a metastatic deposit from a clear cell RCC on FNAC as well as PET scan. The rare presentation in soft tissue should be suspected, which also needs to be differentiated from a benign soft tissue tumor.

Keywords: metastasis, renal cell carcinoma (RCC), soft tissue.

GJMR-K Classification: NLMC Code: QZ 202



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Keywords: metastasis, renal cell carcinoma (RCC), soft tissue.

I. Introduction

enal cell carcinoma has a widespread and very unpredictable metastatic potential, even after a nephrectomy. Its metastatic potential most commonly extends to lungs, lymph nodes, bones, liver, and brain. In few autopsy series, approximately 0.4% of cases with skeletal muscle metastasis have been reported.⁵ Due to increased use of modern diagnostic modalities of choice like ultrasound and CT scan, diagnosis of RCCs has increased in early stages⁷ and a majority are diagnosed incidentally during an investigation for other disease process of abdomen.⁹ The Classical triad of gross hematuria, pain and a palpable mass in the abdomen is rare accounting to only 6–10%.⁸

Ultrasound and cross-sectional imaging like CT scan and MRI are needed to establish the diagnosis. Treatment of early stages of disease, i.e. localized disease is partial or radical nephrectomy. Recurrent lesion [>10 years] is rare in RCC [4]. The recurrence rates are about 10.5%–21.6% at 15 and 20 years respectively as described by Miyao et al.¹⁰

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II. CASE REPORT

A 57-year-old male patient presented to the FNAC unit of pathology department with complaints of abdominal wall lump for one month. He was a known case of renal cell carcinoma operated in a reputed hospital in 2013. The Patient was on Votrient (Pazopaniba potent receptor tyrosine kinase inhibitor) approved for treatment of renal cell carcinoma.

On examination, he was having an HB value of 14 gms/dl. There was a swelling in the lower abdominal wall which was firm in consistency and measured approximately 2.5 cm in greatest dimension.

FNAC was done and send to The Pathology department. Microscopy showed sheets and clusters of atypical cells with round to oval nuclei & finely granular to clear cytoplasm (Fig.1, 2). Moderate anisokaryosis & atypical bare nuclei also noted.

The patient gave a history of radical nephrectomy 5 years back with a history of left iliac fossa pain for the last few months, following which he received few cycles of chemotherapy (Votrient).

With the previous history of renal cell carcinoma and nephrectomy, the diagnosis of metastatic deposit from a clear cell RCC was given on cytopathology.PET SCAN was done which revealed a large lobulated FDG avid heterogeneously soft tissue mass with perilesional infiltration in left lumbar region & an FDG AVID nodular mesenteric soft tissue deposit in left iliac fossa measuring 2.3 x 2.1 cms.

III. Discussion

Renal cell carcinoma is the most common primary renal malignant neoplasm in adults and accounts for approximately 90% of renal tumors which makes up to 3% of all adult malignancies. Although advancements in diagnostic procedures have led to early detection of RCC, a third of patients newly diagnosed with RCC are still found to have metastatic disease at the initial presentation. Furthermore, about half of patients who are successfully nephrectomized suffer metastases to several organs during follow up. Solitary metastasis develops in 1/3rd of cases of RCC, which is normally localized at the time of initial diagnosis. The most common sites of distant metastasis

are lungs (50%), lymph nodes (35%), liver (30%), bone (30%) and adrenal gland (5%).

Soft tissue metastasis is usually a very rare phenomenon.RCC is reported to have a widespread and unpredictable metastatic potential, in spite of a curative nephrectomy. Late recurrence is a very unusual presentation of this tumor.³ In a study of Mc Nichol's⁶, 11% of metastatic RCC cases occurred more than ten years after the initial diagnosis, even after total resection. Making a diagnosis of metastatic RCC to the soft tissues is very challenging because the differential diagnosis is a soft tissue tumor. It is important to differentiate the two, as aggressive surgical resection is necessary for metastatic RCC, but not for benign soft tissue tumor. RCC is characterized by high signal intensity in T1 and T2 weighted images, which helps to differentiate it from primary soft tissue tumors³.

Pazopanib is an oral angiogenesis inhibitor targeting the VEGF receptor, PDGF receptor, and c-KIT. In a recent prospective randomized trial of pazopanib versus placebo in treatment-naive or cytokine-treated m RCC patients, there was a significant improvement in progression-free survival and tumor response, 9.2 months vs. 4.2 months¹¹.

IV. Conclusion

The incidence of metastatic renal carcinoma is increasing. The overall prognosis of a patient with advanced RCC is poor, emphasizing the importance of early detection and prompt treatment of a primary lesion in its early stage. Rare sites of metastasis should be considered in the differentials of a soft tissue setting, with a known history of RCC. Biopsy finding of a clear cell lesion should also arouse the suspicion of a clear cell RCC metastasis.⁴

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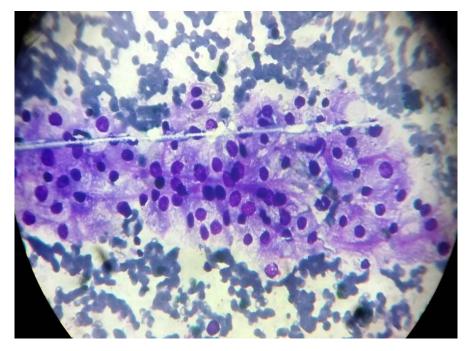


Fig.1: Cluster of cells with clear cytoplasm1

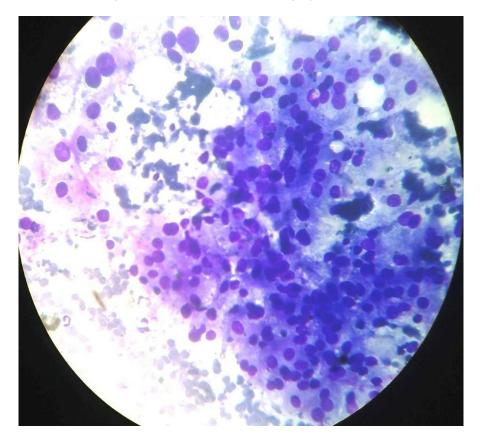


Fig. 2: Clusters of cells (under40X)



Fig. 3: PET scan with FDG avid area in iliac FOSSA 1

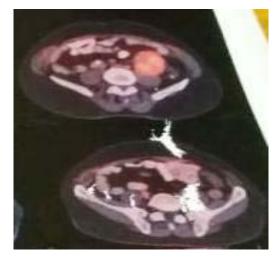


Fig. 4: PET scan with FDG avid area in iliac FOSSA 2



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Ex-vivo Hair Growth Promotion Efficacy of Biofield Energy Treated Williams Medium E using Vibrissae Hair Follicle Organ Culture

By Dahryn Trivedi & Snehasis Jana

Abstract- Hair follicle growth and maturation are potentially useful for the treatment of skin injuries and diseases. For this consequence, the present study has investigated the potential of the Biofield Energy Healing (The Trivedi Effect®) Treated test item (William's Medium E) on the vibrissae hair follicle organ culture cells for the assessment of hair cell growth and development in vitro. The test item was divided into two parts. One part was denoted as the untreated test item without any Biofield Energy Treatment, while the other part was defined as the Biofield Energy Treated test item, which received the Biofield Energy Healing Treatment by renowned Biofield Energy Healer, Dahryn Trivedi. The study parameters like bulb thickness and formation of telogen were assessed using cell-based assay with the help of UTHSCSA Image tool version 3.

Keywords: biofield energy healing, consciousness energy healing treatment, the trivedi effect[®], telogen, vibrissae hair follicle cells, bulb thickness, skin health.

GJMR-K Classification: NLMC Code: WR 450



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Abstract- Hair follicle growth and maturation are potentially useful for the treatment of skin injuries and diseases. For this consequence, the present study has investigated the potential of the Biofield Energy Healing (The Trivedi Effect®) Treated test item (William's Medium E) on the vibrissae hair follicle organ culture cells for the assessment of hair cell growth and development in vitro. The test item was divided into two parts. One part was denoted as the untreated test item without any Biofield Energy Treatment, while the other part was defined as the Biofield Energy Treated test item, which received the Biofield Energy Healing Treatment by renowned Biofield Energy Healer, Dahryn Trivedi. The study parameters like bulb thickness and formation of telogen were assessed using cellbased assay with the help of UTHSCSA Image tool version 3. The experimental results showed that the untreated test item group showed 20% and 26.67% increased bulb thickness on day 5 and 7, respectively compared to the day 1. Besides, the percent of telogen follicle in the Biofield Energy Treated test item group exhibited 57%, 86%, and 100% on day 3, 5, and 7, respectively compared to day 1. The overall results demonstrated that the Biofield Energy Treatment has the potential for hair growth promotion as evident via increased the formation of telogen. Therefore, the Biofield Energy Healing (The Trivedi Effect®) Treatment might be useful as a hair growth promoter for various treatment of skin injuries and skin-related disorders like necrotizing fasciitis, actinic keratosis, sebaceous cysts, diaper rash, decubitus ulcer, etc. Keywords: biofield energy healing, consciousness energy healing treatment, the trivedi effect®, telogen, vibrissae hair follicle cells, bulb thickness, skin health.

I. Introduction

he hair follicle is consist of mainly two components one is epithelial components and the others are dermal components. Hair growth is regulated by the division of the hair follicle matrix cells under control of the dermal papilla. Three different stages of hair growth can be identified, an active phase (anagen) during which hair growth occurs, an intermediate regressive (catagen) stage and a resting phase (telogen) during which no cell proliferation occurs [1]. Numerous assays are routinely used to assess hair growth, while hair follicle organ culture model is one of the most popular and powerful *in vitro* systems [2]. With the measurement of follicular activity in terms of bulb

thickness and improvement of anagen initiation, regression of catagen, and finally shifting of hair bulb i.e., telogen formation is the main criteria for hair growth [3]. The positive control used in this experiment i.e., minoxidil because many literature reported that it can directly promote hair growth via the stimulation of growth factor release from adipose-derived stem cells dermal papilla and epithelial cells [4]. In recent years, several scientific reports and clinical trials have revealed the useful effects of Biofield Energy Treatment, which have shown to enhance the immune function in cases of cervical cancer patients via therapeutic touch [5], massage therapy [6], etc. Complementary and Alternative Medicine (CAM) therapies are now rising as preferred models of treatment, among which Biofield Therapy (or Healing Modalities) is one approach that has been reported to have several benefits to enhance physical, mental and emotional human wellness. However, as per the data of 2012 from the National Health Interview Survey (NHIS), which indicated that the highest percentage (17.7%) of the Americans used dietary supplements as a complementary health approach as compared with other practices in past years. The National Center of Complementary and Integrative Health (NCCIH) has recognized and accepted Biofield Energy Healing as a CAM health care approach in addition to other therapies, medicines and practices such as natural products, deep breathing, yoga, Tai Chi, Qi Gong, chiropractic/osteopathic manipulation, meditation, massage, special diets, homeopathy, progressive relaxation, guided imagery, acupressure, acupuncture, relaxation techniques, hypnotherapy, healing touch, movement therapy, pilates, rolfing structural integration, mindfulness, Ayurvedic medicine, traditional Chinese herbs and medicines, naturopathy, essential oils, aromatherapy, Reiki, and cranial sacral therapy. Human Biofield Energy has subtle energy that can work effectively [7]. CAM therapies have been practiced worldwide with reported clinical benefits in different health disease profiles [8]. This energy can be harnessed and transmitted by the experts into living and non-living things via the process of Biofield Energy Healing. Biofield Energy Treatment (The Trivedi Effect®) has been published in numerous peer-reviewed science journals with significant outcomes in many scientific fields such

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as cancer research [9, 10], microbiology [11-14], biotechnology [15, 16], pharmaceutical science [17-20], agricultural science [21-24], materials science [25-28], nutraceuticals [29, 30], skin health, human health and wellness.

Based on the literature information and importance of Biofield Energy Healing Treatment on various fields, the authors sought to evaluate the impact of the Biofield Energy Treatment (The Trivedi Effect®) on the test item (William's Medium E) for hair cells growth activity with respect to the assessment of different hair growth parameters like bulb thickness and telogen formation using standard assays in vibrissae hair follicle organ culture cells with the help of UTHSCSA Image tool version 3.

II. Materials and Methods

a) Chemicals and Reagents

William's Medium E (phenol-free) with growth factors, antibiotics solution (penicillin-streptomycin), and DMEM (phenol-red free) were procured from HiMedia, India. Minoxidil sulphate (positive control) was purchased from Clearsynth Labs Ltd., Mumbai. L-glutamine and fungisone were procured from Gibco, India. Insulin from bovine pancreas, hydrocortisone, vitamin B_{12} , and glucose were obtained from Sigma Chemical Co. (St. Louis, MO). All the other chemicals used in this experiment were analytical grade procured from India.

b) Isolation and Maintenance of Vibrissa Hair Follicles from Mice

Vibrissa hair follicles were isolated from 16 days old C57BL/6 mice by micro dissection using standard method with few modifications [32]. Briefly, both the left and right whisker pads of C57BL/6 mice were excised out and placed in a 1:1 solution of Earle's balanced salts and phosphate-buffered saline supplemented with 100U penicillin per mL and 100 mg streptomycin per mL. After that, individual anagen follicles were isolated from the whisker pad and were randomized into different groups and transferred on to a 5 cm plastic petri dish containing Earle's balanced salts solution/PBS (1:1) using one dish per animal. Isolated anagen follicles were maintained in a 24 well plate in William's medium E (supplemented with growth factors) for a period of 7 days and maintained at 37 °C at 5 % CO₂ [33]. William's Medium E (phenol-free) with growth factors was used as a test system in the present study. Vibrissae hair follicle culture was maintained under William's Medium E growth medium for routine culture supplemented with 10% FBS [34].

c) Experimental Design

Isolated anagen follicles were grouped into following treatment groups. Group 1 was served as untreated test item (William's Medium E cells phenol-

free supplemented with growth factors). Group 2 was defined as Biofield Energy Treated William's Medium E. Group 3 was denoted as the positive control, minoxidil sulphate (1 mM).

d) Biofield Energy Healing Approach

The William's Medium E has used a test item in this experiment. The test item was divided into two parts. One part was considered as the untreated test item. where no Biofield Energy Healing Treatment was provided. Further, the untreated test items group was treated with "sham" healer for comparison purpose. The sham healer did not have any knowledge about the Biofield Energy Healing Treatment. Second part of the test item was received Biofield Energy Healing Treatment (known as The Trivedi Effect®) under laboratory conditions for ~5 minutes through Dahryn's unique Biofield Energy Transmission process to the test item. Biofield Energy Healer in this study did not visit the laboratory, nor had any contact with the test samples. After that, the Biofield Energy Treated and untreated test items were kept in similar sealed conditions and used for the study as per the study plan.

e) Morphological Analysis of Vibrissa Hair Follicles

All the follicles in the well plate were observed daily through microscope for any morphological changes. Photographs of the individual vibrissae follicles were captured during the course of the study upto day 7. After the completion of the experiment, all the follicles treated with test items and positive control were measured for hair bulb thickness and compared to the respective baseline thickness of day 1 using UTHSCSA Image tool version 3.

f) Statistical Analysis

Data were represented as mean \pm standard error of mean (SEM). For statistical analysis Sigma-Plot (version 11.0) was used as a statistical tool. Statistically significant values were set at the level of $p \le 0.05$.

III. Results and Discussion

a) Assessment of Vibrissa Hair Follicles

Human hair growth is a unique repetitive cycle that composed of the stage of initiation (anagen), regression (catagen), and shifting of hair bulb (telogen) phases [34]. This cycle of hair growth, regulating hair development and periodic regeneration is influenced by dermal papilla cells (DPCs); while if the DPCs are in a pathological state that ultimately leads to various hair loss disorders [35-37]. Topical minoxidil is a well-established therapeutic for various types of hair growth-related disorders like alopecia [38]. The vibrissae hair follicle organ culture cells were treated with the positive controland the untreated test item (William's Medium E). The percent increased of bulb thickness of both minoxidil sulphate and the untreated test item groups are shown in Figure 1.

The experimental results showed that the bulb thickness in the positive control (minoxidil) group was 1.9 \pm 0.29, 2.6 \pm 0.37, and 3.3 \pm 0.36 mm on day 1, 5, and 7, respectively. Additionally, the untreated test item group showed 1.5 \pm 0.45, 1.8 \pm 0.57, and 1.9 \pm 0.60 mm of bulb thickness on day 1, 5, and 7, respectively. Overall, the bulb thickness was significantly increased

by 36.84% and 73.68% in the minoxidil group on day 5 and 7, respectively compared to the day 1. Moreover, the untreated test item group showed 20% and 26.67% increased bulb thickness on day 5 and 7, respectively compared to the day 1 (Figure 1). Follicles were observed to have catagen-like changes with an increase in hair bulb thickness measurement (Figure 3 A).

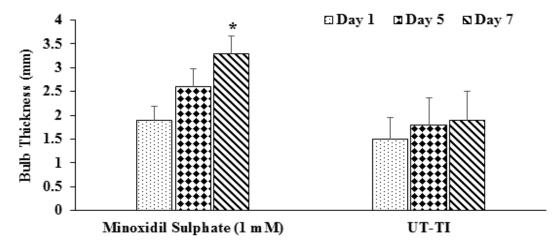


Figure 1: Assessment of hair follicle growth and development in William's Medium E in terms of bulb thickness (mm) on vibrissae hair follicle organ culture cellsof positive control and untreated test item groups. UT-TI: Untreated test item (William's Medium E). Values are expressed as Mean \pm SEM. *p \leq 0.05 vs. day 1.

Besides, the Biofield Energy Treated test item (William's Medium E) on vibrissae hair follicle organ culture cells and the percent of telogen follicles are shown in Figure 2. The percent of telogen follicle was observed as 57%, 86%, and 100% on day 3, 5, and 7, respectively in the Biofield Energy Treated test item group (Figure 2). On day 7, shifting of the hair shaft from its original place was observed in the seven out of seven folliclei.e., 100%, which is a hallmark of telogen

transition (Figure 3 B). Follicles kept in minoxidil sulphate solution led to increase in hair bulb thickness in follicles when observed on day 5 as well as day 7 as compared to day 1. In the untreated test item group, follicles was maintained their integrity with slight increase in hair bulb thickness observed on day 5 and 7 as compared to day 1.

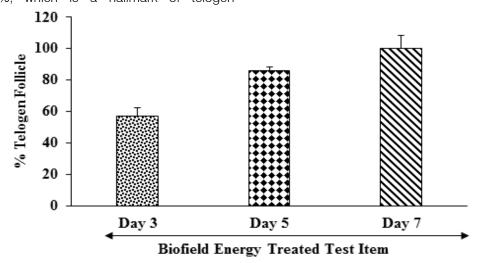


Figure 2: Effect of the Biofield Energy Healing Treatment on vibrissae hair follicle organ culture cells for the assessment of hair follicle growth and development in William's Medium E in terms of telogen formation of Biofield Energy Treated test item (William's Medium E).

Overall, the untreated test item group did not show any telogen formation, however the Biofield Energy Treated test item significantly exhibited telogen formation *i.e.*, promote hair growth upto day 7 observation. Based on that it is assumed that in this

experiment the improvement of hair cell growth and development in terms of telogen formation could be due to the impact of The Trivedi Effect® - Biofield Energy Healing Treatment.

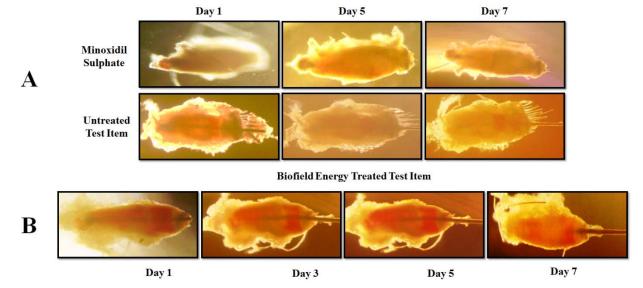


Figure 3: Representative photomicrograph of various stages of hair follicle development (anagen - catagen - telogen) of different treatment groups. A: Initiation of anagen follicle (thick hair bulb) in minoxidil and untreated groups; B: Transformation of initiation, regression of hair bulb, and shifting of hair shaft (telogen follicle) in the Biofield Energy Treated test item (William's Medium E) group.

IV. Conclusions

The experimental results showed that the untreated test item group showed 20% and 26.67% increased bulb thickness on day 5 and 7, respectively compared to the day 1. Besides, the percent telogen follicle was found as 57%, 86%, and 100% on day 3, 5, and 7, respectively in the Biofield Energy Treated test item group as compared to day 1. Overall, the Biofield Energy Treated test item significantly enhanced hair follicles regarding telogen formation compared to the untreated test item group in vibrissae hair follicle organ culture cells derived from mice. In conclusion, The Trivedi Effect® - Consciousness Energy Healing Treatment might act as an effective hair growth enhancer and it can be used as a complementary and alternative treatment for the prevention of various types of skin-related disorders viz. necrotizing fasciitis, actinic keratosis, sebaceous cysts, diaper rash, decubitus ulcer etc. Besides, it might be useful to improve cell-to-cell communication, normal cell growth, cell differentiation, neurotransmission, cell cycling and proliferation. health, hormonal balance, skin immune cardiovascular functions. Besides, it can also be utilized in organ transplants (for example kidney transplants, liver transplants and heart transplants), hormonal imbalance, aging, and various immune-related disease conditions such as Ulcerative Colitis, Alzheimer's Disease, Dermatitis, Irritable Bowel Syndrome, Asthma, Hashimoto Thyroiditis, Pernicious Anemia, Sjogren

Sclerosis, Syndrome, Multiple **Aplastic** Anemia. Hepatitis, Diverticulitis, Graves' Disease, Dermatomyositis, Diabetes, Myasthenia Gravis. Parkinson's Disease, Atherosclerosis, Systemic Lupus Erythematosus, stress, etc. with a safe therapeutic index to improve overall health, and quality of life.

Abbreviations: CAM: Complementary and Alternative Medicine; PBS: Phosphate-buffered saline; DPCs: Dermal papilla cells; UT-TI: Untreated test item.

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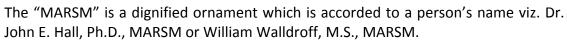
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- 17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.
- 18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.
- 19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



- **20.** Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.
- 21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.
- **22. Report concluded results:** Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.
- **23. Upon conclusion:** Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium though which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

The introduction: This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.



Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- o Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

Introduction:

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.



The following approach can create a valuable beginning:

- o Explain the value (significance) of the study.
- o Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

Approach:

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

Procedures (methods and materials):

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- o To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- o Simplify—detail how procedures were completed, not how they were performed on a particular day.
- o If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- o Resources and methods are not a set of information.
- o Skip all descriptive information and surroundings—save it for the argument.
- o Leave out information that is immaterial to a third party.



Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- o Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- o In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- o Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- o Do not present similar data more than once.
- o A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."



Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- o You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- o Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- o Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

THE ADMINISTRATION RULES

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Topics	Grades		
	А-В	C-D	E-F
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring



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