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Date of Admission to the Course:
27th April 2022

Title of the Study/ Dissertation:

COMPARATIVE STUDY OF CORNEAL ENDOTHELIAL CELL COUNTS AFTER PHACOEMULCIFICATION IN DIFFERENT GRADES OF CATARACT

Brief Resume of the Intended work

Introduction:

Cataract is the leading cause of preventable blindness in the world. According to WHO, Blindness is major health problem in which visual acuity less than 3/60 (Snellen's chart)[1]. Cataract remains the single largest cause of blindness. There is an estimated figure of 17.6 million (39%) people worldwide who are blind because of curable cataract[2]. NPCB definition of blindness. Under national programme for control of blindness (NPCB) in India, blindness is defined as presenting distance visual acuity of < 6/60 or central visual fields < 20° in the better eye.[3]

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In India, approximately 5 million cataract surgeries are performed per year; therefore, it is important to determine the safest surgical technique for the endothelium. There is a paucity of data from India on the effect of small-incision cataract surgery (SICS) and phacoemulsification on the corneal

endothelium (morphological and functional) was performed to assess the postoperative endothelial cell loss and change in endothelial morphology over a short period of time between the two commonly performed cataract techniques .Modern cataract surgery aims to achieve a better unaided visual acuity with rapid post-surgical recovery and minimal surgery related complications. Early visual rehabilitation, better unaided visual acuity and surgical safety can be achieved in a great measure by reducing the incision size. Incision size depends on the mode of nucleus delivery and the type of intraocular lens used. It is about 10-12 mm in standard extra capsular surgery, about 5.5mm to 7.0 mm in manual small incision surgery and 3 mm to 5.5 mm in Phacoemulsification, depending upon the technique and implant. Phacoemulsification the ideal technique for cataract surgery and the preferred done where the resources are available[5]

Phacoemulsification is now commonly used surgical procedure for cataract. The endothelial cell damage during phacoemulsification can be caused by factors such as irrigation flow, turbulence and movement of fluids, presence of air bubbles, direct trauma caused by the instruments or lens fragments, and the phacoemulsification time and power needed to achieve nuclear emulsification. Grade of nucleus sclerosis affect the corneal endothelial cell loss in phacoemulsification [6]

The corneal endothelium is a monolayer formed by polygonal, mainly hexagonal cells, whose size and shape are uniform in normal conditions. These cells are the key to maintaining corneal deturgescence, necessary for clear vision Trauma or other insults often cause endothelial cell death, which is irreparable because these cells lack division capacity .When endothelial cell density diminishes, the remaining cells increase in size to cover the empty spaces left by the dead cells, and therefore there is a change in the size (polimegatism) and morphology (pleomorphism) of the remaining cells. The normal density of corneal endothelial cells varies between 2,500 and 3,000 cells/mm2 in adults. When this density falls

below a threshold level of 400 to 700 cells/mm2 , there is corneal edema, and vision is compromised. Although there is a subtle cell loss with age, severe cell loss is usually the result of intraocular surgery. With the development of corneal specular microscopy, it was possible to assess corneal endothelial cell loss “in vivo”. Cataract surgery, trabeculectomy and combined phacoemulsification, intraocular lens implantation and trabeculectomy cause endothelial cell loss [18]

Specular microscopy and corneal pachymetry were performed in both eyes of 537 normal Indian volunteers, aged 20-87 years. Parameters studied included endothelial cell density, cell area, coefficient of variation (CV) in cell area and hexagonality. Mean endothelial cell density in the study population was 2,525 +/- 337 cells/mm2. There was a statistically significant decrease in endothelial cell density with age ($p < 0.001$, correlation -0.387) and the rate of cell loss was 0.3% per year. There was also a statistically significant increase in mean cell area ($p < 0.001$, correlation 0.362) and CV ($p = 0.02$, correlation 0.096), and decrease in percentage of hexagonal cells ($p = 0.01$, correlation -0.127) with increasing age. There was no significant difference in these parameters between fellow eyes of subjects. In all age groups, the mean endothelial cell density was significantly lower than values reported previously in the Japanese population. The values were less than those described in the American population, but the differences were statistically significant only in the 20-30 and 41-50 year age groups. Normative data for the endothelium in the Indian population are reported. Endothelial cell density in Indian eyes is less than the values described in the Japanese and American populations[20]

Specular microscopy is a diagnostic modality for imaging the corneal endothelium that allows for direct observation of the endothelial cell morphological characteristics either in a clinic or eye bank setting. Endothelial imaging using a specular microscope is routinely used in the assessment of endothelial health in various endothelial diseases, evaluation of the donor cornea prior to keratoplasty and postoperative follow-up after keratoplasty [19]

Incidence of endothelial cell loss seems to increase with increase in nucleus hardness from 12.6% in grade I to 16.7% in grade IV with average cell loss of

14.5%. ECLoss was greater in immediate postoperative period and in 1st week.[21]

PRIMARY RESEARCH QUESTION: What is the impact on corneal endothelial cell Counts after Phacoemulsification surgery?

SECONDARY RESEACH QUESTION 1: Does Different Grades of Cataract have any relation with Corneal Endothelial Cell Counts after Phacoemulsification Surgery?

SECONDARY RESEACH QUESTION 2: NIL

PRIMARY HYPOTHESIS: Corneal Endothelial Cell Counts decreases after Phacoemulsification

SECONDARY HYPOTHESIS: Comparable loss of Corneal Endothelial Cells takes place after Phacoemulsification with respect to different grades of Nuclear stages.

OTHER HYPOTHESIS 2: NIL

REVIEW OF LITERATURE

Corneal endothelial damage following manual small incision cataract surgery and Phacoemulsification is surgery still major concern of modern day cataract surgery. Introduction of different techniques and certain innovation in various instrument have reduced corneal endothelial loss. Shrikant Deshpande & Aarti Aagrwal showed that both the group found out significant increase in central corneal thickness on postoperative day 7 indicating some endothelial cell disturbance. Also endothelial cell loss in both the group were comparable[7]

Hyung Bin Hwang, Byul Lyu, Hye Bin Yim, and Na Young Lee have found out loss of endothelial cells in some groups post phacoemulsification after 2 months in different ACD(anterior chamber depth groups)[8]

Budiman, B study shows increase of central corneal thickness depend on degree of endothelial cell trauma , corneal edema ,decrease in function of Na - K-ATPase endothelial pump[9]

Deshpande, S., Agarwal, A., Shah, P., & Gala, Y and his team worked on 101 operated patient of cataract by manual SICS & PHACO showed increase in corneal thickness on day 8but the change in CCT value was comparable between two surgical procedure groups. Also endothelial cell loss were comparable[10]

Mohamed AE Soliman Mahdy,Mohamed Z Eid,Mahmoud Abdel-Badei Mohammed,Amr Hafez, andJagdish Bhatia that Microcoaxial phacoemulsification was efficient in removing noncomplicated cataracts; however

a statistically significant endothelial cell loss was noted, especially with increased nuclear hard- ness. This endothelial cell loss was mostly related to the increased cumulative dissipated en- ergy (CDE), aspiration time, and volume of balanced salt solution used.[11]

Ken Hayashi MD,Hideyuki Hayashi MD , Fuminori Nakao MD, Fumihiko Hayashi MD has said that Both univariate and multivariate analyses identified the firmness of the nucleus as the most significant risk factor for endothelial cell loss. Therefore, mechanical contact with nuclear fragments is considered the principal cause of endothelial injury.[12]

Nayak, B. K., & Shukla, R. O have mentioned that a variable degree of endothelial cell loss happens after intraocular surgeries such as cataract extraction and phakic intraocular lens implantation. As a result of this, endothelial cell density is lower and mean cell area larger in pseudophakic eye versus the normal age-matched cell density or the opposite eye without any intraocular intervention.[13]

Raghda Faisal Abdelfatah Mutwali , Abd Elaziz Mohamed Elmadina and team has concluded that Phacoemulsification causes significant damage to corneal endothelium cells, including decrease in corneal endothelial cell density, hexagonality and cell number [14]

Bourne, R. R. A., Minassian, D. C., Dart, J. K. G have found that Phacoemulsification carried a significantly higher risk (OR: 3.7, P = 0.045) of severe cell loss in the 45 patients with hard cataracts [15]

Islam, Q. U., Saeed, M. K., & Mehboob, M. A and Ewete, T., Ani, E. U., & Alabi, A. S have found out that in addition to endothelial cells loss, the hexagonal

shape of individual endothelial cellis decreased with mean total loss of about 24.1% and the mean coefficient of variation of cell size is increased after phacoemulsification. These changes in shape and size are attributed to enlargement of endothelial cells in order to fill the gaps as a result of endothelium cell damage. Previous studies also support these findings. , this result in agreement with that reported in literature [16 17]

AIMS AND OBJECTIVES:

PRIMARY OBJECTIVES: To measure the Corneal Endothelial Cells in pre & postoperative patient of cataract undergoing Phacoemulsification surgery.

OTHER OBJECTIVES 1: To compare the change in Corneal Endothelial Cell counts in follow up patient of Phacoemulsification surgery.

OTHER OBJECTIVE 2: NIL

MATERIALS AND METHODS: This will be a prospective study which will be conducted in the Department of Ophthalmology in a tertiary care hospital of Maharashtra.

STUDY DESIGN:-Interventional type of Comparative study.

STUDY SETTING:-Tertiary Care Hospital in Maharashtra.

STUDY POPULATION:-Patients undergoing cataract surgery

Phacoemulsification surgery.

SAMPLE SIZE:-120

(Sample size 112 & above [7.5% margin of error], [95% confidence level] matching the inclusive criteria**)**

SAMPLING TECHNIQUE: Simple randomized technique.

STUDY PERIOD:-

METHOD OF STUDY SELECTION

INCLUSION CRITERIA :

- Age : 50-70 Years.
- Patient who goes through surgery without any intra-operative complication.
- Patient having cataract with grade 2 nuclear sclerosis and grade 3 nuclear sclerosis
- Patient without any intraocular pathology.
- Patient without glaucoma.
- Patient with no pre existing corneal pathology.
- Patient who were willing to undergo a follow up for a period of postoperative 28 day.

EXCLUSION CRITERIA :

1) Any deviation in the operative steps other standard.
2) Previous corneal surgery.
3) Scarred conjunctiva.
4) Keratoconus, Lenticonus & Corneal Dystrophy.
5) History of ocular trauma or postoperative trauma.
6) Patient's having Pterygium with cataract.
7) Failure to follow up.

METHOD OF DATA COLLECTION:

1. Patients who are undergoing cataract surgery in ACPM MEDICAL COLLEGE DHULE.

2. A written informed consent in patient's own language will be taken from those willing to participate in the study and will be screened according to the inclusion and exclusion criteria.

3. Demographic factors like age, sex, occupation &address will be recorded as per the attached proforma.

4. Detailed history of patient will be taken.

5. Ocular examination shall be carried out by

- SNELLENS VISUAL ACUITY Chart for testing vision and preoperative refraction was performed.
- SLIT LAMP For detail anterior segment examination and grading of cataract.
- Posterior segment evaluate by indirect ophthalmoscopy.
- TOPCON SP-1P (Specular microscopy) For measuring the Corneal endothelial cell count
- Keratometry using Bosch and Lomb keratometer will be done.
- Biomedix A scan for axial length.
- ALCON INFINITY BIOMEDIX machine for Phacoemulsification surgery.
- IOP measurement by Goldmann applanation tonometry.

6) All the routine blood investigations (CBC, BT,CT, HIV, HBsAg, BSL(FASTING/POST PRANDIAL), URINE ROUTINE MICROSCOPY) will be done and physician fitness will be obtained before posting the patient for cataract surgery.

7) All 100 patient will be operated by single surgeon. The patient will be selected by randomization method and divided into Group A (Nuclear Sclerosis Grade 2) &
Group B (Nuclear Sclerosis Grade 3)

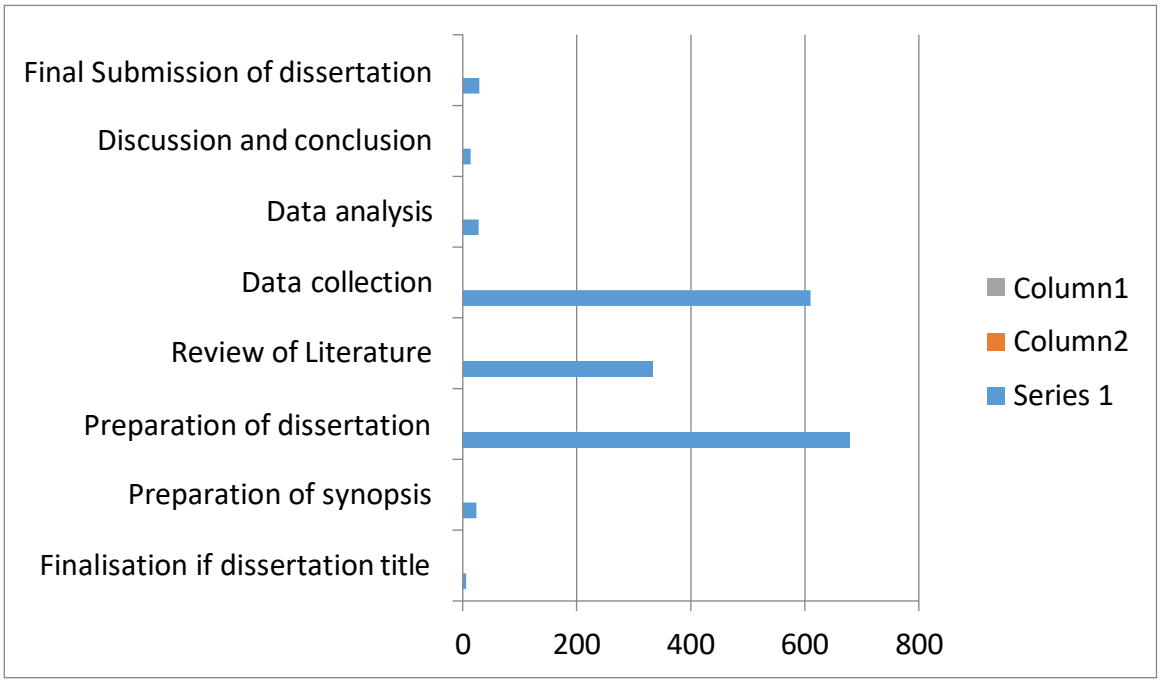
FOLLOW UP: The patients will be followed up at post op. 1week, 28 day for ocular examination related Corneal Endothelial Cell Count the test conducted will be Specular Microscopy

ETHICS COMMITTEE CLEARANCE: Ethics committee clearance was obtained before start of study. Written and informed consent will be taken from all the patients before undertaking the study.

TIMELINE OF STUDY-

TIME LINE CHART

Task name	**Start date**	**End date**	**Duration**
Finalization of dissertation title			
Preparation of synopsis			
Preparation of dissertation			
Review of Literature			
Data Collection			
Data analysis			
Data presentation			
Discussion and conclusion			
Submission of dissertation			
Final submission of dissertation			
Total duration			


Final Submission of dissertation
Discussion and conclusion
Data analysis
Data collection
Review of Literature
Preparation of dissertation
Preparation of synopsis
Finalisation if dissertation title
0
200
400
600
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Column1
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Series 1

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APPENDIX A1:

Informed Consent Form

दिन ांक-
संमती पत्र
मी ---------- वय ---------- वर्षे,
र हण र ---------- म झ्य स्वेच्छेने य अभ्य स प्रकल्प त सहभ गी होण्य स
सांमती िेत आहे.
म झ्य वर प्रस्ततु अभ्य स Small incision cataract surgery क ंवा
Phacoemulsification ऑपरेशन नंतर बुबुळाच्या जाडीमध्ये होणाऱ्या बदलाची तुलना रणे य
प्रकल्प मध्ये सहभ गी होण्य स कोणत ही िब व न ही व म झ्य नक र मुळे म झ्य उपच र त ब ध
येण र न ही.
उपच र िरम्य न सांभ व्य धोकय ांची म दहती मल स ांगण्य त आलेली आहे/मी व चलेली आहे व
य अभ्य स िरम्य न करण्य त येण्य ऱ्य तप सण्य , और्षधोपच र घेण्य स मी तय र आहे.
य अभ्य स िरम्य न ननघण रे ननष्कर्षष के वळ श स्त्रीय क रण ांस ठी व परले ज तील अथव
प्रक शशत के ले ज तील य ची मल कल्पन आहे तसेच म झी ओळख क यिशीर ब बी व्यनतररकत इतर
वेळेस गुप्त ठेवली ज ईल.
य प्रकल्प मधून मी कधीही ब हेर पडू शकतो/शकते य ची मल म दहती आहे. प्रस्ततु
प्रकल्प ची सवसष ध रण म दहती मल समजेल अश भ र्षेत मी व चली आहे/मल समज वून स ांगण्य त
आली आहे.
मल मर ठी व चत येते/मर ठी व चून ि खववलेली समजते.
सहभ गी व्यकतीची सही/ड व अांगठ अभ्य स करण ऱ्य डॉकटर ांचे न व
सही
प लक ची सही/ड व अांगठ प्रमुख म गिष शकष डॉकटर ांचेन व
सही
स क्षीि र चे न व व न ते ववभ ग प्रमुख डॉकटर ांचे न व
सही/ड व अांगठ सही

INFORMED CONSENT FORM

I, Mr. / Mrs._____, age__years, residing at____hereby give my informed consent to participate in the "COMPARATIVE STUDY OF CORNEAL ENDOTHELIAL CELL COUNTS AFTER PHACOEMULCIFICATION IN DIFFERENT GRADES OF CATARACT" study.

- There is no compulsion on me to participate in this Study and I am giving my free consent for it.
- I am ready and willing to undergo all tests, treatment & surgical procedures in the present Study.
- I have read and I have been explained the general information and purpose of the present Study.
- I have been informed / I have read the probable complications while participating in the present Study.
- I know that I can withdraw from the present Study at any time.
- Any data or analysis of this Study will be purely used for scientific purpose and my name will be kept confidential except when required for any legal purpose.
- I was informed in detail about the surgical procedure to be performed and the possible outcome as well as side effects of the procedure in my mother tongue by the concern doctor.

Signature of Volunteer_____

Signature of parent/ relative_____

Witnesses:

1._____

2. _____

Signature of Principal Investigator_____

APPENDIX A2:

NAME:

IPD/OPD:

AGE:

SEX:

ADDRESS:

TELEPHONE NUMBER:

OCUPATION:

PRESENTING COMPLAINTS:

HISTORY OF PRESENTING ILLNESS:

PAST HISTORY:

PERSONAL HISTORY:

FAMILY HISTORY:

GENERAL EXAMINATION:

TEMPERATURE:

PULSE:

RESPIRATORY RATE:

BLOOD PRESSURE:

SYSTEMIC EXAMINATION:

CVS:

CNS:

RS:

PA:

OCULAR EXAMINATION:

RE **LE**

Visual acuity:

Unaided:

Pinhole:

Near:

Aided vision:

Auto Refractometry:

BCVA: pre-operative

Post-operative

Head posture:

Orbit:

Eyebrow:

Eyelid:

Position:

Lid margin:

Eyeball:

Position:

Size of eyeball:

Movement of eye ball:

Extraocular movements:

Conjunctiva:

Sclera:

Cornea :

Anterior chamber:

Iris:

Pupil:

Lens:

Intraocular pressure:

Sac syringing:

DDO:

SPECIAL INVESTIGATIONS:

	CORNEAL ENDOTHELIAL CELLS COUNTS (CECC) BY PHACOEMULCIFICATION SURGERY IN N.S GRADE 2 CATARACT	CORNEAL ENDOTHELIAL CELLS COUNTS (CECC) BY PHACOEMULCIFICATION SURGERY IN N.S GRADE 3 CATARACT
PREOPERATIVE CECC		
POST OPERATIVE CECC DAY 1ST		
POSTOPERATIVE		

CECE DAY 7TH		
POST.OPERATIVE CECC DAY 28TH		

CECC : CORNEAL ENDOTHELIAL CELL COUNT

STUDY OF SURGICAL MANAGEMENT OF PROXIMAL 1/3RD TIBIA FRACTURE IN ADULT WITH EXPERT NAIL

A SYNOPSIS SUBMITTED TO

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES

FOR THE AWARD OF MASTER OF SURGERY IN

ORTHOPAEDICS

(M. S. ORTHOPAEDICS)

BY

DR. AJAY VIJAY PAWAR

UNDER THE GUIDANCE OF

DR.SHAILENDRA PATIL

ASSOCIATE PROFESSOR

DEPARTMENT OF ORTHOPAEDICS

JMF'S ACPM MEDICAL COLLEGE, DHULE

STUDY OF SURGICAL MANAGEMENT OF PROXIMAL 1/3RD TIBIA FRACTURE IN ADULT WITH EXPERT NAIL

INTRODUCTION:

Fracture of the tibia is a common long bone injury due to high energy trauma occurring secondary to motor vehicle accidents and fall from height with an annual incidence of 26 per 1,00,000 individuals [1,2]. Due to the tibia's presence in subcutaneous location, its structural anatomy, and sparse anteromedial soft tissue coverage, the tibia is subjected to frequent injuries. It is also commonly associated with compound fractures than any other long bone in the body [3].

Various treatment modalities present for the management of tibia fractures include both conservative and surgical methods. The conservative method comprises of closed reduction and cast application, which commonly results in delayed union, malunion, and restricted range of motion at the ankle and knee joint [4]. To reduce the complications associated with conservative treatment, there is an increasing trend towards surgical management, which involves methods like open reduction and internal fixation with plates, Intramedullary Nailing (IMN), and external fixation, each having their own indications, advantages, and disadvantages [5-7]. The preferred surgical modality for such fractures is Intramedullary fixation, being less invasive, load sharing, preserves extra-osseous blood supply, and fracture haematoma [8-11].

With the advent of new modern implants like Expert Tibia Nail, an anatomically customised IMN system which allows multidirectional interlocking of nail below the tibia plateau, thereby facilitating the surgeon to address and fix very proximal tibia fractures [12].

Option of multidirectional locking and end caps, which blocks the most proximal oblique screw, helps attain absolute angular stability. Thus, expert tibia nailing system has led to significant advancement in the fixation of proximal tibia fractures.

The aim of this study will be surgical management of proximal 1/3rd tibia fracture in adult with expert nail.

REVIEW OF LITERATURE:

Faisal A et al analyse and assess the functional and radiological outcome of expert tibia nailing used for treating extra-articular proximal-third tibia fractures. All these patients had extra-articular proximalthird tibia fractures and were managed with expert tibia nail. All patients underwent clinical and radiological evaluation based on the Klemm and Borner scoring system at a regular interval of six weeks, three months, six months, and at one year. The most common mode of injury was road traffic accidents (80.64%). Patients were in the age group of 26-63 years with an average mean of 41.80±9.7 years. The male to female ratio was 4.16:1, suggestive of male predominance. According to the Klemm and Borner scoring system, 71.42% of patients belonged to the excellent group, 17.85% were in good, 7.14% in fair and 3.57% in poor. Radiological union was achieved in an average period of 20.9±2.09 weeks. In this study, scores obtained on the basis of Klemm and Borner scoring system, depicts that intramedullary expert tibia nailing is a good treatment modality for the management of extra-articular proximal-third tibia fractures, which provides good angular stability and adequate fixation resulting in early rehabilitation and union with excellent functional outcome and mere complications. It is also a safer treatment modality in case of compromised surrounding soft tissue. [13]

Uduthala Sai Kiran et al studied functional outcome of proximal 1/3rd, tibial fractures in adults operated with expert tibial nailing. It was observed, 87% of patients achieved good or excellent results, fair results were obtained in 3 (10%) patient and poor result in one (3%) patient. 2 (6%) patients had malunion, 2 (6%) patients had delayed union, 1 (3%) patient had deep infection led to implant failure. Intramedullary nailing is a safe and effective technique for the treatment of tibial metaphyseal fractures. It avoids the additional soft-tissue dissection associated with traditional open procedures as well as the complications associated with external fixators. Expert tibial nail can give excellent functional and clinical results. Complications such as failure of the bone-implant construct or post-operative malallignment are avoidable if careful pre-operative planning is allied with meticulous surgical technique. [14]

Ramesh Chand Meena et al done study to compare plating and nailing options in proximal tibia extra-articular fractures. Postoperative hospital stay (p = 0.035), time to full weight-bearing, and union time (p = 0.004) were significantly less in the IMN group than in the PTP group, but there was no clear advantage of either technique in terms of operative time (p = 0.082), infection rate (p = 0.738), range of motion of the knee (p = 0.462), or degrees of malunion and nonunion. Both implants have shown promising results in extra- articular proximal tibial fractures, and provide rigid fixation that prevents secondary fracture collapse.[15]

AIMS & OBJECTIVES:

Aim:

- To study functional outcome of surgical management of proximal 1/3rd tibia fracture in adult with expert nail

Objectives:

- To study incidence of proximal 1/3rd tibia fracture in adult age group.
- To study clinical profile of proximal 1/3rd tibia fracture in adult age group.
- To study functional outcome of proximal 1/3rd tibia fracture in adult age group.
- To study complications of surgical management of proximal 1/3rd tibia fracture in adult with expert nail

MATERIALS AND METHODS

- **Study Type:** Prospective observational study.
- **Study Place:** Department of Orthopaedics, Tertiary care Hospital.
- **Study population:** Patients with proximal 1/3rd tibia fracture.
- **Sampling Technique used:** Simple random sampling
- **Study Period:** Two Year
- **Study duration:** 2022-2024
- **Sample Size:** A total sample size of 40 patients with proximal 1/3rd tibia fracture satisfying inclusion and exclusion criteria.

Sample Size Estimation

With z of 1.96 and precision of 0.1, using proportion of proximal 1/3rd tibia fractures as 10% reported by Benirschke SK et al **[2]**, using below mentioned formula, the minimum sample size calculated was 40.

Thus, it was planned to enroll minimum 40 cases of proximal 1/3rd tibia fractures for the present study.

$$n = p\left(1 - p\right)\left(\frac{Z}{E}\right)^2$$

Where-

Z: z-statistics for desired level of confidence (i.e., *0.05) (1.96 for 95% CI)*

p: The estimate of Expected proportion with the variable of interest in the population *(0.1)*

E: The precision level *(0.1)*

Inclusion criteria

- Patients with age >18 years with proximal 1/3rd tibia fracture.
- Both gender.
- Gustilo Anderson type I and type II fractures.

Exclusion criteria

- Patients with age <18 years
- Gustilo Anderson type III fractures.
- Patients unfit for surgery
- Not willing to participate.

Informed Consent:

- Informed consent was taken from all patients before the start of the study.

Material:

- Information regarding basic demographics, mechanism of injury, and Gustilo Anderson classification will be noted.
- All patients will receive preoperative prophylactic antibiotics.
- Manual reduction preoperatively will be done after giving general anaesthesia.
- Patients then will undergo expert nail fixation.
- The patients will be discharged on the third postoperative day and kept on regular follow-ups.
- A clinical and radiological assessment will be performed at 1 st and 3rd week.
- All patients will be functionally assessed with Klemm Borner's criteria and complications, if any, will be documented. X-ray leg AP and lateral view taken.

STATISTICAL DATA ANALYSIS:

Statistical analysis will be done using the SPSS software package. Mean and standard deviation will be calculated for quantitative variables like age, surgery duration, knee movements. Frequencies with percentages will be computed for qualitative variables. A chi-square test will be used for dichotomous values, and t tests will be done for continuous values. $P<0.05$ will be considered as significant difference.

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Time frame of study

TIME LINE CHART

Task name	Start date	End date	Duration
Finalization of dissertation title			
Preparation of synopsis			
Preparation of dissertation			
Review of Literature			
Data Collection			
Data analysis			
Data presentation			
Discussion and conclusion			
Submission of dissertation			
Final submission of dissertation			
Total duration			

Annexure

PROFORMA

PATIENT PROFILE

1.Patient name

2.Age/sex

3.Address

4.Date of trauma

5.Side of fracture

6.Mode of injury

7.Type of fracture

8.Date of admission

9.Chief complaints

10.Signs and symptoms

11.Past history

12. Lab reports

13.Date of surgery

14.Inter-operation finding

15.OT procedure

16.Post operation orders

17.Date of discharge

18.Follow up

[a]Fracture Union

[b]Movements

[c]Complication – deformity, limb length discrepancy, etc

[d]Harris hip score

Informed Consent Form

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Informed Consent Form

Name:

Age:

Sex:

Address:

Op/Ip No.:

Doctor's Name:

I, the undersigned Mr./Mrs._____,

Through this letter consent to voluntarily participate as a participant in the following study "surgical management of proximal 1/3rd tibia fracture in adult with expert nail"

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

I agree that my participation in this study is voluntary.

I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.

I understand that my identity will not be revealed.

I understand that the data collected during the study might be used for further research work and publication purposes.

I have fully explained about locking compression plate implant and its complications.

I have explained about blood transfusion if needed during procedure and its complications

Patient’s signature/thumbprint

Date:

1)Witness signature/thumbprint.

Relation:-

Date:-

2)Witness signature/thumbprint

Relation:-

Date:-

Doctor’s Signature

Date:-

PG Guide signature

Date:-

HOD signature

Date:-

JMF's ACPM Medical College, Dhule

Name of the Postgraduate Student:
Dr.Ketki R. Deotale

Name of the Guide and Designation:
Dr.S. P.Wadgaonkar
HEAD OF THE DEPARTMENT

Course and Subject of Specialization:
M.S.Ophthalomology

Date of Admission to the Course:
18th NOVEMBER 2022

Title of the Study/ Dissertation:

COMPARATIVE STUDY OF IOP MEASURED BY GOLDMAN APPLANATION TONOMETER AND NON CONTACT TONOMETER

Brief Resume of the Intended work

Introduction:

Intraocular pressure (IOP) is an important measurement, which should be taken in every patient over the age of 40 that undergoes a complete ophthalmic examination and in all patients with ocular hypertension (OHT) or with risk factors for developing primary open-angle glaucoma (POAG) (i.e., family history, myopia, increased cup-to-disc ratio, etc.). IOP measurement is obviously a fundamental tool in subjects with diagnosed ocular hypertension or glaucoma. Even if the IOP measurement in vivo is only an estimate of the true IOP (which is only possible with invasive manometry), this value, rightly or wrongly, is often taken as an indicator of the efficacy of any treatment for glaucoma and to assess glaucoma severity and progression in patient management. It is thus of great importance to acquire accurate and precise IOP measurements in clinical practice.[1]

Aqueous humor is secreted by the ciliary process to the posterior chamber and goes through the pupil to the anterior chamber (inflow). It then

leaves the anterior chamber through the trabecular meshwork to the venous system (outflow). Normally, there is equilibrium between inflow and outflow that creates normal intraocular pressure (IOP). Any circumstances that affect the formation of aqueous humor or outflow of aqueous humor cause changes in IOP. Local and systemic disorders, medicines, and ocular surgeries affect IOP. Higher IOP levels are associated with ganglion cell and nerve fiber layer loss. The progression of damage eventually involves the optic nerve and irreversible visual loss.[2]

Glaucoma is the second leading cause of blindness worldwide.The only prevent able risk factor for the development and progression of glaucoma is IOP. The treatment of glaucoma focuses mainly on lowering intraocular pressure (IOP).[10] Correctly measuring IOP is very important in diagnosing glaucoma and conducting follow-ups. Medical, laser, or surgical treatments of glaucoma concentrate on lowering IOP.[2.] Earlier studies have shown that every 1 mmHg drop in IOP decreases visual field damage by 10%.5 Therefore, precise measurements are very important. The ideal device must be easy to use, rapid, safe, and precise, irrespective of patient posture or age.[2] Tonometry or the measurement of IOP, the pressure of the fluid inside the eye is usually the only modifiable factor in management of all types of glaucoma.[10]

Numerous instruments, called tonometers, have been proposed since the 19th century to obtain IOP measurements. Based on the operating principle, these instruments can be differentiated into two main groups: (1) indentation tonometers; (2) applanation tonometers.[1]

Indentation Tonometry:

The prototype of the indentation tonometers is the Schiøtz tonometer that was introduced many years ago .Using this instrument, the cornea is indented by a plunger loaded with different weights. The IOP is based on the depth of indentation. The values are shown on a scale ranging from 0 to 20

units, in which the protrusion of the plunger of 0.05 mm represents each unit of measurement. The value indicated on the handle needs to be converted in mmHg using a conversion scale The coefficient of ocular rigidity, which can differ amongst eyes, should be taken into consideration to obtain corrected measurements of IOP.[1]

The Schiøtz tonometer is a simple and relatively inexpensive instrument. It is still sometimes used in developing countries and in children under general anesthesia. This tonometer, however, is subject to several sources of error, which include improper positioning on the eye, defective or dirty instruments, high variability in comparison with other devices and measurements influenced by individual ocular rigidity. Moreover, patients must be in a supine position when taking measurements with this tonometer [1]

2 .Applanation Tonometry :

Applanation tonometers are currently considered the most reliable instruments for an accurate IOP measurement. Such tonometers use the Imbert–Fick law: P = F/S, in which P is pressure, S represents the surface of the flattened area, and F is the force needed to flatten a fixed corneal area. Apart from the tonometer by Maklakoff and several other instruments that are no longer currently in use, in which the force is provided by the weight of the tonometer itself, applanation tonometry is based on the area of flattened cornea that is calculated and converted in mmHg. In almost all instruments of this type, the F value is varied to get the proper corneal applanation for a predetermined area. The Goldmann applanation tonometer (GAT) was first invented in 1948 by Hans Goldmann and is still considered the gold standard to date. The tonometer needs to be positioned on a slit lamp. A truncated cone, with a 7.35 mm2 surface area and a diameter of 3.06 mm, illuminated by a blue light, is pushed on the center of the anaesthetized cornea. A doubling prism embedded in the cone divides the circular meniscus on the surface of the flattened cornea e into two arcs, which need to be aligned in order to obtain a precise and standardized applanation. The force used needed to flatten the corresponding surface of the cornea is directly proportional to the IOP, expressed in mmHg that can be directly

read in the scale of the measuring drum or in the posterior window for the digital version Contrary to what Hans Goldmann believed, corneal thickness may show a significant effect on IOP measurements. Thin corneas can give rise to an underestimation of the IOP and vice versa. Several authors have tried to address this problem by proposing a number of correction formulae however, none have been shown to be of widespread use. Several corneal biomechanical properties, which are not all completely known, may be involved, thus rendering the proposed correction factors misleading and limiting their clinical use Studies have reported that a thin cornea can be a factor of risk for developing glaucoma, in addition to the underestimated IOP with GAT.

GAT it is still the tonometer most commonly used in clinics, thanks to the ease of use, accuracy, reproducibility and affordability. There are, however, several drawbacks that should be kept in mind. GAT is affected by parameters of the cornea, which include central corneal thickness when this is far from the average (540 microns) in addition to corneal curvature, axial length, hysteresis, etc. Moreover, GAT measurements are subjective and can depend on the physician experience. Studies have reported that even for the same physician, clinically significant differences can be found with a 95% repeatability coefficient of ±2 mmHg Other possible errors and drawbacks are due to the tear film with too little or too much fluorescein or an irregular or scarred cornea. GAT needs to be positioned on a slit lamp, and the subject must be in an upright position. It is also important to remember that topic anesthesia is needed and that GAT should be periodically calibrated to provide good precision .[1]

Non-Contact Tonometry (Air-Puff Tonometry):

Non-contact tonometry (NCT) was first designed by Zeiss and developed by Grolman in 1972 Several models have been proposed in the past few decades that use a pulse of air to flatten the cornea without the need for touching the eye such models, therefore, do not require anesthesia or fluorescein drops.

The device has auto puff control (APC), which provides a quieter and softer puff of air for the patient’s comfort. If the first puff is too strong, the device automatically

uses a softer puff of air. This device takes about 10 seconds to measure the IOP of both eyes. The screen shows the results of three measurements, and their average for each eye is obtained by pressing a button three times.[2]

The pros of NCT are mostly based on the ease of use, non-contact nature and portability of several devices. Measurements can be taken by non-medical staff and patient compliance is relatively good in most cases NCT does not require slit-lamp positioning; thus, it is easily used in cases with elderly individuals, children, disabled patients and patients with limited collaboration. NCT can be considered for patients that may not tolerate topical anesthetics, patients with limited collaboration or those at greater risk of infection.[1]

NCT could be helpful in a day-to-day clinical setting that involves dealing mostly with normal patients undergoing routine checkups. This type of tonometry can be ideal as a screening tool, which can easily be performed by non-medical staff.

NCT can prove to be useful for post-operative patients with lid edema, limited collaboration, ocular pain, discomfort and increased tear film meniscus size, which are all factors that influence proper GAT measurements.[1]

PRIMARY RESEARCH QUESTION: What is the difference in IOP measured by goldmann applanation tonometer and non contact tonometer?

SECONDARY RESEACH QUESTION 1: Is NCT a appropriate alternative for goldmann applanation tonometer in measuring IOP?

PRIMARY HYPOTHESIS: There is a difference between IOP measured by Goldmann applanation tonometer and Non contact tonometer

REVIEW OF LITERATURE:

Attaullah Shah Bukhari, Abdul Haleem Mirani, Muhammad Ali Shar, Shahid Jamal Siddiqui Liaquat Ali Shah in their study proved that IOP with APT is slight higher about 3 mm Hg but is safe and easy than GAT tonometry. There is no fear of spread of infection and it can be used in mass screening program.[5]
Hidayatullah Mahsud1 , Muhammad Wali Saleem , Rafiq Muhammad , Muhammad Saleem , Mirqad Ayaz proved that APT is commonly used for IOP measurement. There is a reasonably good for tonometers at IOP within the normal range.[4]

Ihsan Yilmaz, Cigdem Altan, Ebru Demet Aygit, Cengiz Alagoz, Okkes Baz, Sibel Ahmet, Semih Urvasizoglu, Dilek Yasa & Ahmet Demirok proved that The NCT is easier and faster to use than the GAT and readings with an NCT may be undertaken by non medical and unlicensed personnel under the supervision of a doctor.[2]

Ricardo Alexandre Stock Carine Ströher Rodrigo Rosa Sampaio Rafael André Mergener Elcio Luiz Bonamigo conducted study which proved that the NCT used was a valid alternative to the GAT, which is considered the gold standard.[3]

Stephen J Vincent, Roslyn A Vincent , David Shields and Graham A Lee proved that there were strong correlations between the intraocular pressure measurements obtained with Goldmann and non-contact tonometers .[6]

Turki M. Almurbrad, Kelechi Ogbuehi prove that the average (and SD) IOP measured with the Goldmann tonometer in the first session (14.8 ± 2.9-mmHg) did not vary significantly from the IOP measured with the non-contact tonometer (pre-applanation) in both sessions or with the average Goldmann IOP in the second session.[7]

Ajit K Joshi1 , Indrajit Shinde1, Amit Pathak proved in their study NCT can be considered as a good screening tool for evaluation of glaucoma. [8]

Dr. Kilari Sindhu, Dr. Iqra Mushtaq , Dr. Abhay Lune , Dr. Aditya Ganesh, Dr. Aparna , Dr. Shivamsh Reddy conducted a study and that NCT being a non-invasive technique can be used routinely as a screening procedure.[9]

AIMS AND OBJECTIVES:

AIM: To determine the difference between IOP measured by goldmann applanation tonometer and NCT

PRIMARY OBJECTIVE: To asses weather NCT is an appropriate alternative for goldmann applanation tonometer for measuring IOP.

MATERIALS AND METHODS: This will be a prospective study which will be conducted in the Department of Ophthalmology in a tertiary care hospital of Maharashtra.

STUDY DESIGN:- observational type of Comparative study.

STUDY SETTING:-Tertiary Care Hospital in Maharashtra.

STUDY POPULATION:-Patients coming to out patient department of

ophthalmology for regular eye checkup

SAMPLE SIZE:-

From medical records identified average population with ophthalmic and ocular complaints is about 15,000 and as per previous studies conducted in various parts of Maharashtra IOP measurement in cases of glaucoma is 10.6%.[3]

Based on this and putting this in formula of cross sectional sample size formulation with confidence limit of 5% , expected frequency 10.6 %, population size15,000 and confidence level 95% ,

SAMPLE SIZE : 150

(Sample size 150 & above [7.5% margin of error], [95% confidence level] matching the inclusive criteria**)**

SAMPLING TECHNIQUE: Cross sectional sample size formulation technique

STUDY PERIOD:-

METHOD OF STUDY

SELECTION INCLUSION

CRITERIA :

- Age : 40-70 Years.
- Patient without any intraocular pathology.
- Patient without glaucoma.
- Male and females

EXCLUSION CRITERIA

1) Patients with corneal opacities, corneal dystrophies, corneal perforation.
2) Infective pathologies like ulcers, uveitis, corneal degenration
3) Patients with corneal edema, corneal ectatic conditions.
4) Patients who have undergone any ocular surgeries.
5) Patients with posterior segment pathologies like retinal detachment, vitreous hemorrhages
6) Patients not willing to be a part of study.

METHOD OF DATA COLLECTION:

1. Patients who are coming in out patient deparment of ophthalmology ACPM MEDICAL COLLEGE DHULE.

2. A written informed consent in patient's own language will be taken from those willing to participate in the study and will be screened according to the inclusion and exclusion criteria.

3. Demographic factors like age, sex, occupation &address will be recorded as per the attached proforma.

4. Detailed history of patient will be taken.

5. Ocular examination shall be carried out by

- SNELLENS VISUAL ACUITY Chart for testing vision and preoperative refraction was performed.
- SLIT LAMP For detail anterior segment examination and grading of cataract.
- Posterior segment evaluate by indirect ophthalmoscopy.
- IOP measurement by Non contact tonometer..
- IOP measurement by Goldmann applanation tonometry.

6) All patient will be examined by same doctor. The patient will be selected by randomization method and divided into Group

FOLLOW UP: The patients will be followed up after one week and IOP will be examined.

ETHICS COMMITTEE CLEARANCE: Ethics committee clearance was obtained before start of study. Written and informed consent will be taken from all the patients before undertaking the study.

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TIMELINE CHART

Stages of thesis project	February 2023	March-April 2023	May-June 2023	July 2023	July 2023 - February 2025	April-May 2025
1) Selection of thesis topic						
2) Institutional ethics committee approval						
3) Review of literature						
4) Online submission of synopsis to MUHS						
5) Data collection and tabulation of records						
6) Compilation and analysis of data						
7) Write-up and final thesis submission						

APPENDIX A1:

INFORMED CONSENT FORM

I, Mr. / Mrs._____, age_____years, residing at_____hereby give my informed consent to participate in the "COMPARATIVE STUDY OF IOP MEASURED BY GOLDMANN APPLANATION TONOMETER AND NON CONTACT TONOMETER" study.

- There is no compulsion on me to participate in this Study and I am giving my free consent for it.
- I am ready and willing to undergo all tests, treatment .
- I have read and I have been explained the general information and purpose of the present Study.
- I have been informed / I have read the probable complications while participating in the present Study.
- I know that I can withdraw from the present Study at any time.
- Any data or analysis of this Study will be purely used for scientific purpose and my name will be kept confidential except when required for any legal purpose.
- I was informed in detail about the procedure to be performed and the possible outcome as well as side effects of the procedure in my mother tongue by the concern doctor.

Signature of Volunteer_____

Signature of parent/ relative_____

Witnesses:

1. _____

2. _____

Signature of Principal Investigator_____

APPENDIX A2:

NAME:

IPD/OPD:

AGE:

SEX:

ADDRESS:

TELEPHONE
NUMBER:

OCUPATION:

PRESENTING COMPLAINTS:

HISTORY OF PRESENTING

ILLNESS: PAST HISTORY:

PERSONAL

HISTORY: FAMILY

HISTORY: GENERAL

EXAMINATION:

TEMPERATURE:

PULSE:

RESPIRATORY

RATE: BLOOD

PRESSURE:

SYSTEMIC

EXAMINATION: CVS:

CNS:

RS:

PA:

OCULAR EXAMINATION:

	RE	**LE**
Visual acuity:		
Unaided:		
Pinhole:		
Near:		
Aided vision:		
Auto Refractometry:		
BCVA: pre-operative		
Post-operative		
Head posture:		
Orbit:		
Eyebrow		
: **Eyelid:**		
Position:		
Lid margin:		
Eyeball:		

Position:

Size of eyeball:

Movement of eye ball:

Extraocular movements:

Conjunctiva:

Sclera:

Cornea :

Anterior chamber:

Iris:

Pupil:

Lens:

Intraocular pressure:

GAT

NCT

Sac syringing:

JMF's ACPM Medical College Dhule

Performa for Submission of Synopsis to BORS

Name of the postgraduate student:

Dr.BHUMICA BALKISAN SABLE

Name of the Guide and Designation:

UNDER THE GUIDANCE OF

DR. SHAILENDRA PATIL

PROFESSOR

DEPARTMENT OF ORTHOPAEDICS

JMF'S ACPM MEDICAL COLLEGE, DHULE

Course and subject of Specialization:

M. S. ORTHOPAEDICS

Date of admission to the course:

04-11-2022

Title of the Study / Dissertation:

A PROSPECTIVE STUDY OF EXTRA-ARTICULAR DISTAL END RADIUS FRACTURES MANAGEMENT BY CLOSE REDUCTION WITH PERCUTANEOUS KIRSCHNER WIRE FIXATION

INTRODUCTION

Distal end radius fractures is one of the most common fractures of the upper limb treated by orthopedic surgeons, accounting for about 8-15% of all bony injuries.[1] The fracture pattern shows a bimodal age distribution with peaks in early adolescence and again in older age, it is characteristically seen with an increasing incidence with increasing age. Females have an eight fold increased lifetime risk of sustaining a fracture compared to males, , and also a higher incidence in areas with a high prevalence of osteoporosis.[2]

The fracture of the distal radius typically happens because of a fall on an outstretched hand.[3]

Types of Distal radius fractures-

Colles' fracture specifically is defined as metaphyseal injury of cortico-cancellous junction (within 2−3 cm of articular surface) of the distal radius with characteristic dorsal tilt, dorsal shift, radial tilt, radial shift, supination and impaction.

Smith's fractures, also referred to as reverse Colles' fracture, have palmar tilt of the distal fragment.

Barton's fracture is the displaced intra-articular coronal plane fracture-subluxation of dorsal lip of the distal radius with displacement of carpus with the fragment. Reverse Barton's occurs with wrist in palmar-flexion and involves the volar lip.

Chauffer's fracture was described as originally occurring due to backfire of the car starter handles in older models. It involves an intra-articular fracture of radial styloid of variable size.[4]

Treatment strategy -percutaneous pinning, which involves the percutaneous (through the skin) insertion of pins or wires, which may or may not be threaded. This is considered less invasive, quicker or often less technically demanding than open surgery, where the fractured bone is exposed to direct view. In percutaneous pinning, the reduction of the fracture is closed - such as Kirschner wires - may be used to manipulate the fracture fragments.[5]

The most common techniques for percutaneous pinning using K-wires are interfragmentary and Kapandji's configurations.

The simplest method of K-wire insertion is the interfragmentary or transstyloid technique, known eponymously as Willenegger and Guggenbuhl [6]which involves the insertion of two or more K-wires into the radial styloid in an oblique plane that crosses the fracture and is buried in the opposite diaphyseal cortex; this technique is often enhanced by the insertion of a dorsoulnar K-wire to create a cross-pin configuration. [7]

The Kapandji technique was designed to use the K-wires as a buttress to prevent dorsal translation of the distal fragment of the radius by insertion of the K-wire perpendicular to the axis of the radius and directly into the fracture site. [8] The wire is then inclined to an oblique plane and drilled into the opposite cortex. Traditionally, this technique used three wires of which one was inserted dorsolateral to the fracture and the remaining two from the dorsal aspect. [9] The Fritz-modified Kapandji technique involves the insertion of two intrafocal K-wires and a third through the styloid process which acts to hold the distal fragment in place for a more rigid configuration than the buttress wires alone.[10]

REVIEW OF LITERATURE:

During ancient times over the period of Hippocrates and Galen, distal radius fractures (DRFs) was considered to be simple wrist fracture dislocations. But **Claude Pouteau** (1725–1775) the famous French lithotomist first varied from these thoughts as he described about forearm fractures in the French literature, including a distal radius fractures. On behalf of him, distal radius the French people coined it as pouteau fractures[11].

Next an Irish surgeon **Sir Abraham Colles** in volume of Edinburgh Medical Surgical Journal described distal third radius fractures. Before the invention of radiography he made a brief accurate description about the distal radius fractures based on just he clinical examinations. On behalf of his contributions, british people termed this as - colles fractures.[11].

John Rhea Barton (1794-1871), orthopaedic surgeon worked in Pennsylvania Hospital in Philadelphia (United States of America) described about the fractures with intraarticular involvement that was later termed as volar and dorsal barton fractures.

Robert William smith (1807-1873) Irish surgeon decribed about the smith fractures. French speaking world called it as the "Goyrand Fracture" after the famous French orthosurgeon Jean-Gaspar-Blaise Goyrand (1803–1866) who made excellent papers for distal radius anatomy and mechanism causing individual fractures.

British Orthopaedic Surgeon, **Jonathan Hutchinson (**1828–1913) described the fracture involving the radial styloid process with intraarticular extension and displacement.

In 1951, **Gartland** and **Werley** published a detailed evaluation and classification system based on metaphysical comminution, intra- articular extension and displacement.

In 1959, **Lidstrom** outlined a classification based on fracture line, direction and degree of displacement, extent of articular involvement and involvement of DRUJ.

In 1965, **Older** proposed a classification that incorporated radial shortening as variable in classification.

In 1967, **Frykman** identified the importance of ulnar involvement and publish a classification based on involvement of radiocarpal and radioulnar joints and the ulnar styloid fracture.

In 1984, **Melone** heralded the contemporary era of classification by stressing the careful delineation of 4 components of radio carpal joint namely radial shaft, radial styloid, dorsal medial and volar medial fragments.

In 1993, **Fernadez** classification was introduced, which was designed to be practical, determine stability, include associated injuries and provide general treatment recommendations.

External fixation was first described by **Anderson and O' Neil.** Practice involving bridging devices were described by **Oddly,.** The first report of by **Ombredanne** in 1930 described distal radius external fixation with the use of a nonbridging device[11]

Sebastian V. Gehrmann, MD, Joachim Windolf, MD, Robert A. Kaufmann (march 2008).

"Functional outcome of distal radius communited fractures with percutaneous pinning in low and high demand groups'. Study was done in about Forty-one patients with average age of 65 years and were reviewed. The patients into segregated into low-demand groups and high- demand groups. The study results suggested that the k- wire management of distal radius fractures in elderly patients had a good functional outcome.

Uzzaman KS (2005)

"Comparative study of conservative versus Percutaneous Pinning for Comminuted Distal Radius extra and intraarticular Fractures "study involves postmenopausal women of 35 to 70 age group. A study was done in with unstable Frykmann type III-VIII distal radius fractures for Forty patients resulting from a trivial fall. The results proved that best anatomic reductions, radiological parameters and the mayo functional outcome scores were obtained by percutaneous pinning than plaster alone Stability of the reduction was maintained and the chances of re displacement further fracture collapse is also less with percutaneous pinning.[12]

Gupta, Rakesh, MS; Raheja, Anil, MS; Modi, Umesh, (Jul 1999)

"Randomized prospective comparative trial study of percutaneus cross pin fixation and plaster in functional position versus conventional plaster of paris immobilization. Study done with 50 patients comparing the ability to maintain anatomical reduction and early mobilization. The anatomical reduction with acceptable criteria and functional outcome mayo score results were statistically significant for percutaneus crossed configuration of pin fixation than the plaster cast at final 1 year follow up[13]

MD Sanjiv H. Naidu,MD John Capo.T(1997)

A prospective randomized study on k -wire pinning for the distal radius fractures". This was a biomechanical study. Extra-articular distal radius fractures that are fixed with percutaneous pinning were biomechanically tested. Radial styloid process was fixed with two parallel pins towards the medial cortex and placement of a another crossed pin from the ulnar end of the radius towards the radial intact cortex. Results showed that the percutaneus crossed pin configuration formed the stable construct resisting shear stress, torsion stress and bending stress [14]

Munson, Gregory o. M.D.; Gainor, Barry J. M.D (dec 1981)

"Prospective cohart study of percutaneous pinning in managing high velocity distal radius injury". Study period was three years in a sample of 22 patients. Crossed k –wire pin configuration of percutaneous fixation was done 16 patients had good results and excellent for five patients. One had a complication of pin site infection. He concluded that percutaneous pinning offers good results in treating instable fractures and preventing further collapse[15]

Cherian Jacob (2014)

"A randomized prospective trial of functional outcome with percutaneous Pinning for displaced radial fractures". Study sample was 15 patients. Patients were followed for period of 5 months. MAYO scoring was used to assess functional outcome. Study concluded with good and excellent results in 33 % of pinning group and good functional outcome in 60 % patients. Radiological parameters were maintained in 94 % cases. Pinning with atleast 5 k wires were done and an additional pin for ulna was also applied in this study [16]

Prof . Azzopardi MD (Jan 2005)

Randomised prospective comparative study of Unstable extra- articular distal radial fractures by plaster versus plaster with additional pinning". Patients fixed with intrafocal k –wire had good radiological parameters of radial inclination, radial height, radial shift, palmar tilt compared to plaster alone after 1 year follow up. long term functional outcomes were almost similar percutaneous pinning is an excellent tool to reduce and fix unstable fractures[17]

M.Akhter Baig(2008)

Fixation of wrist distal radius fractures by intrafocal pinning in adults ” Study sample was large with 33 patients. Patients with intra articular or extra articular displaced Colles fractures were fixed with k- wires. The procedure was done according to kapandji technique and k- wire were fixed in basket formation without additional plaster. Concluded that minimally invasive and better stabilization of fracture with k wire and less chances of further redisplacements. Weiland’s criteria were used to access radiological and functional outcome[18]

Primary Objectives

To analyze clinical and functional outcome of Closed reduction with percutaneous Kirschner wire along with immobilisation for extra articular distal end radius fractures.

Other Objective 1

To evaluate the benefits of closed reduction with Percutaneous K wire fixation with immobilisation over closed reduction with immobilisation for management of extra articular distal end radius fractures.

Other Objective 2

To analyze the complications following surgery.

AIMS & OBJECTIVES

Aim:

To evaluate the functional and radiological outcome of extra articular distal radius fractures treated by closed reduction and percutaneous Kirschner wire fixation along with plaster immobilisation.

Objectives:

1. To analyse the role of minimal invasive surgical technique for extra articular distal radius fractures.
2. To evaluate the benefits of closed reduction with Percutaneous K wire fixation with immobilisation over closed reduction with casting only for management of extra articular distal end radius fractures.

MATERIALS AND METHODS

Study Design: Prospective observational study.

Study site: This study will be conducted in tertiary care hospital.

Study Population: All male and female patient having extra articular distal end radius fractures above 18 years of age.

Study setting: This prospective study will be carried out at our tertiary care hospital on cases with inclusion and exclusion criteria between 2023 to 2025

Study Period: Two year

Study duration:2023-2025

Following inclusion and exclusion criteria will be used.

Inclusion criteria:

1. Patient who has been diagnosed as extra articular distal end radius fractures.
2. Patients with more than 18 years of age
3. Patient who are fit for surgery.

Exclusion criteria:

1. Patients with pathological fractures.
2. Patients with intra articular fractures.
3. Patients with less than 18 years of age
4. Polytrauma Patients
5. Patient not willing for surgery
6. Patients unfit for surgery.

Method of collection of data

- By interview
- By follow up at intervals of 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- By clinical examination
- By analysing case papers & Preop and PostOp Xrays

Patients admitted with Distal radius fracture will be examined and investigated with X-ray Wrist with AP and Lateral view (whenever possible). Plaster immobilisation will be applied to all cases.

Outcome measurement:

- All patients will be followed up in clinic at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- Radiographic measurements will be done by orthopedic traumatologists. Antero-posterior (AP) and lateral radiographs (Lat) assessed by PACS software were used for quality of fracture reduction, radial length, radial inclination , dorsal tilt, communition.
- The primary outcome will be measured by time for union (weeks),

  functional outcome (Modified Mayo Wrist score),

  any medical complications including Pin tract infection, pin loosening, superficial radial neuropathy.

Methodology

1. **Study design**

   Prospective observational study.

2. **Study setting**

   This prospective Study will be carried out at our Tertiary care hospital on cases with inclusion and exclusion criteria between 2023 to 2025.

3. **Study population**

   All male and female patients having extra articular distal radius fractures with more than 18 years of age

4. **Sample Size**

   Minimum patients having distal radius fractures.

5. Sampling technique

Simple random sampling

6. **Operational definition**

Closed reduction with Percutaneous K wire fixation a modality for distal radius fractures

7.Methods of measurement

a) Observer technique for collecting radiological data.

b) Measurement of clinical records and associated lab values

c) To assess functional outcome by Modified Mayo Wrist Score

Study requires the following investigations.

- X-ray of the affected Wrist joint in anteroposterior view & lateral view.
- Complete hemogram
- Blood urea
- Serum creatinine
- Serum electrolytes
- Blood grouping and Rh typing
- Bleeding Time and Clotting Time.
- Urine routine
- Random Blood Sugar
- HIV 1 and 2
-HbsAg
- ECG

Before subjecting the patients for investigations and surgical procedures written/informed consent will be obtained from each patient/ legal guardian.

8.Data collection tools

Pre and post operative x-ray

Clinical records

9. **Methods of data collection**

i. Study site:

Department of ORTHOPAEDICS at a tertiary care teaching hospital

ii. Sample population:
All the patients coming to hospital with distal radius fracture and are willing for the study.

iii. **Sample size calculation**:

According to https://jmscr.igmpublication.org/v5-i6/150%20jmscr.pdf

The sample size was calculated using the formula: $\mathbf{n = Z^2 P (1 - P)/ d^2,}$

where Z is the critical value of the Normal distribution (for a confidence level of 95%, the critical value is 1.96),

P = prevalence of 2.84

d is the margin of error, which is considered 5 for the study

Based on the above parameters, the sample size calculated is:

Minimum sample size for the study per group = 58 per & above

Statistical analysis

- After data collection, data entry will be done in a Microsoft Excel sheet.
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed
- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation.
- With the help normality assumption, we use most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant.

10. **Appropriate data management and analysis procedure**

The study is a clinical, prospective and observational study conducted at our institute. After obtaining a detailed history, complete general physical and systemic examination, the patients will be subjected to relevant investigations.

The complete data will be recorded in a specially designed case recording form. The data collected will be transferred into a master chart which is subjected to statistical analysis by the biostatistician. Finally after the diagnosis, the patients are selected for the study depending on the inclusion and exclusion criteria. Post-operatively all cases will be followed up for a minimum period of 6 months.

12. **Data analysis plans and methods**

Statistical analysis of data is carried out by appropriate statistical test

---

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Annexure

PROFORMA

PATIENT PROFILE

1. Patient name

2. Age/sex

3. Address

4. Date of trauma

5. Side of fracture

6. Mode of injury

7. Type of fracture

8. Date of admission

9. Chief complaints

10. Signs and symptoms

11. Past history

12. Lab reports

13. Date of surgery

14. Inter operation finding

15. OT procedure

16. Post operation orders

17. Date of discharge

18. Follow up

[a]Fracture Union

[b]Movements

[c]Complication – pin tract infection,limb length discrepancy, etc

[d]Modified Mayo wrist score

Informed Consent Form

सम्मती पत्र

मी,

नांव :

वय :

लिंग :

पत्ता :

मो. नं.

या सम्मती पत्रा द्वारे लिहून देतो / देते कि मला होणाऱ्या परिणामाचे मला समजविले आहे.व मला यासाठी का निवडण्यात आले ते देखील सांगण्यात आले आहे. मी हे समजतो / ते कि या सर्व गोष्टी मुळे मला त्रास होऊ शकतो पण तो माझा आहे. या तपासण्या करून घेतांना माझा फायदा आहे कारण त्या माझ्या आजाराचा निदान करणार आहे. माझी सर्व माहिती हि खाझगी ठेवण्यात येईल व फक्त या संशोधनात वापरण्यात येईल. समझा हि माहिती बहेर वापरण्यात आली तरी माझे नांव कुठे हि येणार नाही.संशोधन दरम्यान मी माझ्या शंका कोणत्याही वेळी दूर करू शकतो / ते तसेच या तपासण्याचा आलेला निदान मला सांगण्यात येईल.उपचारा दरम्यान कोणत्याही ईप्लांट जसेकी(k wire) दिल्यास माझा कोणत्याही प्रकारचा विरोध नसणार.मी या सर्व गोष्टी स्वतःच्या सम्मती ने करत आहे. व मी कधीही यातून बाहेर पडू शकतो. व या माझ्या नाकारा मुळे माझ्या उपचारात बाधा येणार नाही. या संशोधनाच्या दरम्यान संशोधना मुळे मला कोणतीहि इजा झाली आणि ती या संशोधन कालावधीत दर्शवण्यात आली तर मला त्या बद्दल चे उपचार करण्यात येईल.

मला सर्व गोष्टींची पूर्व कल्पना देण्यात आली आहे व मी स्वसम्मती ने या संशोधनात भाग घेत आहे.

पेशंट चे नांव: प्रमुख संशोधक डॉक्टरांची सही

सही व डाव्या अंगठा चा शिक्का

विटनेस / नातेवाईक चे नांव: मार्गदर्शक डॉक्टरांची सही

नाते:

सही व डाव्या अंगठा चा शिक्का

Informed Consent Form

Name:

Age:

Sex:

Address:

Op/Ip No.:

Doctor's Name:

I, the undersigned Mr./Mrs._____,

through this letter consent to voluntarily participate as a participant in the following study

"PROSPECTIVE STUDY OF DISTAL END RADIUS FRACTURES MANAGEMENT BY CLOSE REDUCTION WITH PERCUTANEOUS KIRSCHNER WIRE FIXATION"

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

I agree that my participation in this study is voluntary.

I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.

I understand that my identity will not be revealed.

I understand that the data collected during the study might be used for further research work and publication purposes.

I have fully explained about Kirschner wire implant and its complications.

I have explained about procedure and it's complications.

Patient’s signature/thumbprint

Date:

)Witness signature/thumbprint.

Relation:-

Date:-

2)Witness signature/thumbprint

Relation:-

Date:-

Doctor’s Signature

Date:-

PG Guide signature

Date:-

HOD signature

Date:-

TIMELINE CHART

Stages of thesis project	February 2023	March-April 2023	May-June 2023	July 2023	July 2023 - February 2025	April-May 2025
1] Selection of thesis topic	■					
2] Institutional ethics committee approval		■				
3] Review of literature			■			
4] Online submission of synopsis to MUHS				■		
5] Data collection and tabulation of records					■	
6] Compilation and analysis of data					■	
7] Write-up and final thesis submission						■

JMF's ACPM Medical College Dhule

Name of the postgraduate student:

DR. GUNJAN DEVENDRA FULEY

Name of the Guide and Designation:

UNDER THE GUIDANCE OF

DR. YASHWANT J. MAHALE

PROFESSOR & HEAD

DEPARTMENT OF ORTHOPAEDICS

JMF'S ACPM MEDICAL COLLEGE, DHULE

Course and subject of Specialization:

M. S. ORTHOPAEDICS

Date of admission to the course:

05-11-2022

Title of the Study / Dissertation:

A PROSPECTIVE STUDY OF MANAGEMENT OF

PERITROCHANTERIC FRACTURES OF FEMUR IN LATERAL POSITION

INTRODUCTION

Intertrochanteric fractures have a tremendous impact on both the health care system and society in general, these fractures are disabling injuries that most commonly affect the elderly population. Fractures involving upper end of femur through and in between both trochanters with or without extension into upper femoral shaft[1] are termed as intertrochanteric fracture . Intertrochanteric fracture occur in the elderly population due to trivial trauma, whereas in the younger population it is most often due to high velocity trauma[2,3] .

Intertrochanteric fractures of the femur are extremely common fractures occurring in elderly osteoporotic individuals. Recumbency following a hip fracture is known to be associated with increased mortality in this group of patients. Surgical treatment is now the accepted standard of management to attain acceptable reduction and early mobilization in the elderly osteoporotic individual. [4]

The intertrochanteric fractures mainly divided into two broad categories as Stable and Unstable types. Stable fractures are those which are undisplaced and with intact posteromedial cortex [5] .The unstable intertrochanteric fractures are defined as three-part fractures with an additional posteromedial fragment including the lesser trochanter or four-part fractures with an additional fragment including the greater trochanter.

Subtrochanteric (ST) femur fractures are defined as fractures of the proximal femur that occur within 5 cm of the lesser trochanter.[6]

Subtrochanteric femur fractures are difficult to treat due to strong deforming forces at the fracture site, tenuous blood supply, and the immense load-bearing forces exerted through the peri-trochanteric region. Adequate reduction and stable fixation are paramount when treating these fractures to optimize patient outcomes.[7,8]

There are two different approaches to operate peritrochanteric femur fractures – Supine and Lateral. Majority of the peritrochanteric fractures are operated on the fracture table in supine position. But fixing the patient on fracture table is cumbersome and more time consuming. Positioning of obese patient on a fracture table and securing to footplates of fracture table is still more difficult because of pendulous abdomen and gluteal folds falling by the side. In the case of failed closed reduction, exposure of the fracture site for open reduction is difficult, because the patient is in supine position and hip is in traction while extended. In certain instances, operating surgeon finds some difficulty in operative field to tacle such haemostasis, retraction of soft tissues and greater assistance is required in such conditions. The possibility of side effects of fracture table including injuries like pudendal nerve neuropraxia and perennial pressure sore can be considered.[9,10] All these complications can be minimized with lateral decubitus position.

The aim of study is to understand the functional outcome of peritronteric femur fractures operated with various modalities in lateral position in tertiary care centre.

REVIEW OF LITERATURE:

In 1870 Malgaigne,a French surgeon introduced metal devices embedded in the bone for mechanical stabilisation of fractures.

In 1897 Nicolaysen described medullary fixation of diaphyseal fractures.

In 1931 Smith Peterson used the tri flanged nail made of nonelectrolytic material and cannulated by Johnson in the next year for insertion of guide wire.

Thorton made a side plate called Thorton plate which allows fixation of Cannulated triflanged nail to the shaft in 1937.

In 1937 Rush devised medullary pinning for most difficult fracture problem and published an atlas illustrating relationship between technique and mechanics of flexible pinning.

In 1939 first nailing in humans was done for subtrochanteric fractures.

Kuntscher in 1941 presented at the German surgical society at Hamburg on evidence of intramedullary fixation device. He presented nailing of humerus, femur and tibia. It became more popular after Second World War.

Bohler performed closed nailing in 58 of 61 closed femoral fractures following intramedullary fixation device by Kuntscher who again introduced the technique of widening the medullary cavity by reaming. At first he used hand reamer and later designed a motor reamer with flexible shaft that enabled reaming over a guide to facilitate insertion of thicker nails.

In 1941 E.L.Jewett developed the fixed angle nail plate.

In 1947, Mclaughlin introduced his angle nail plate such that the angle can be changed due to sliding arrangement.

In 1949 Evans discussed unstable intertrochanteric fractures. Boyd and Griffin called attention to subtrochanteric fractures.

Era of Dynamic Hip Screw (DHS) During the early 1950s when the use of Smith Peterson nail and Jewett nail-plate was very common, W. Schumpelick et al. revolutionized treatment of IT fractures by presenting the results of the sliding neck screw of the DHS in 1955[11]

In 1967, Zickel was one of the first to design a double curve customs, intramedullary device for subtrochanteric fracture which obtained one of the highest union and lowest implant failure rates.

In 1974, Ender introduced Condylocephalic nailing with help of image intensifier.

In 1986, Reconstruction nails were developed, were commercialised as Russell-Taylor reconstruction nails (Smith and Nephew, United States). They were designed so that ipsilateral femoral neck-shaft fractures could be fixed by one single implant.

In 1990 How medica introduced a new device , the gamma nail for reverse oblique fractures and those with subtrochanteric extension.

In 1996, AO/ASIF developed the proximal femoral nail (PFN) as an intramedullary device for the treatment of unstable per, inter and subtrochanteric femoral fractures. Pajarinen J et al compared the DHS with a proximal femoral nail (PFN) in 108 patients and the main outcome measure was recovery of ambulation [12]. The patients treated with IM devices had a significantly faster return to preoperative ambulation levels. Nuber S et al evaluated 129 patients with unstable intertrochanteric fractures treated with either a DHS or a PFN [13]. Revision rates were similar between the two groups. However, there was a significantly shorter surgical time, shorter hospital stay, earlier full weight bearing and lesser pain intensity at 6-months post-op in the PFN cohort.

PFNA-II is the modified PFN design meant to match the Asian proximal femoral morphometry. Expandable PFN was designed to retain the mechanical characteristics of a large-diameter nail, to provide the good torsional stability between the femoral neck and shaft obtained by an expendable peg inserted in the femoral head (especially in cases of poor bone quality), and to avoid the need for interlocking screws. . Jin YM

et al concluded that expandable PFN are better implants than DHS and anatomic plates in treating intertrochanteric fractures [14].

In 2003, the proximal femoral nail antirotation (6PFNA) system was put into clinical use by the Association for Osteosynthesis/Association for the Study of Internal Fixation (AO/ASIF). Although the use of the PFNA for treatment of proximal femoral fractures has achieved good clinical efficacy, a series of complications in Asian patients has been reported in the literature. In 2009, the AO/ASIF organization established the characteristics of the PFNA for Asian patients (PFNA-II). Few published reports have systematically assessed the role of the PFNA-II in the stabilization of intertrochanteric fractures. From March 2010 to March 2013, the PFNA-II was applied in the treatment of intertrochanteric fractures in 163 elderly patients.[15]

Pertrochanteric fractures have high morbidity and lead to multiple complications due to prolonged bed rest (bed sores, pulmonary infections). Osteoporosis makes matters worse both for quality of fixation and implant failures. Early fixation and mobilisation has been the treatment of choice in intertrochanteric fracture femur cases [16] . Earlier implants like Dynamic hip screw worked on principle of controlled collapse. These were extramedullary implants which had high failure rates in lateral wall fractures and reverse oblique fracture pattern. Intramedullary implants proved to have biomechanical advantages [17] . In highly comminuted and old intertrochanteric fractures, cemented hip arthroplasties have been reported [18] . Concentration of stress is drastically reduced by the specially designed intramedullary nail tip. The

helical blade in PFNA2 has 2 advantages. It compacts the already weak cancellous bone from the femoral head rather than being removed which happens in femoral screws. It also has more contact surface area with the femoral cancellous bone, than conventional screws. [19]

Primary Objective

To analyse functional outcome of patients with peritrochantericfemur fracture treated by various modalities in lateral position.

Other Objective 1

To evaluate the benefits of lateral position over supine position for management of peritrochanteric femur fractures

Other Objective 2

To analyze the complications following surgery related to lateral position.

AIMS & OBJECTIVES

Aim:

To evaluate the functional outcome in peritrochanteric femur fracture treated with various modalities in lateral position.

Objectives:

1. To assess the stability of fixation and early mobilization of patients.

2. To analyse benefits of lateral position over supine position in Intertrochanteric and Sub trochanteric femur fracture.

MATERIALS AND METHODS

Study Design: Prospective observational study.

Study site: This study will be conducted in tertiary care hospital.

Study Population: All male and female patient having I/T and subtrochanteric femur fracture above 18 years of age

Study setting: This prospective study will be carried out at our tertiary care hospital on cases with inclusion and exclusion criteria between february 2023 to may 2025

Study Period: Two year

Study duration:2023-2025

Following inclusion and exclusion criteria will be used.

Inclusion criteria:

1. Patient who has been diagnosed as having intertrochanteric fractures.
2. Patient who has been diagnosed as having subtrochanteric fractures.
3. Patient who has been diagnosed as having intertrochanteric fractures with subtrochanteric extension.
4. Patients with more than 18 years of age.
5. Patient who are fit for surgery.

Exclusion criteria:

1. Patients with pathological fractures.

2. Patients with less than 18 years of age.
3. Polytrauma Patients.
4. Patient not willing for surgery.
5. Patients unfit for surgery.

Method of collection of data

- By interview
- By follow up at intervals of 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- By clinical examination
- By analysing case papers & Pre-op and Post-Op X-rays

Patients admitted with Intertrochanteric and subtrochanteric fracture will be examined and investigated with X-ray pelvis with both hips AP and Lateral view (whenever possible). Skin traction will be applied to all cases.

Outcome measurement:

- All patients will be followed up in clinic at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- Radiographic measurements will be done by two orthopaedic traumatologists. Antero-posterior (AP) and lateral radiographs (Lat) assessed by PACS software were used for quality of fracture reduction, Neck Shaft Angle (NSA), Tip Apex Distance (TAD) and any implant failure.
- The primary outcome will be measured by time to union (weeks), functional outcome (Harris Hip Score- HHS), any medical complications including Venous Thromboembolism (VTE), surgical complication, and mortality.

Methodology

1. **Study design**

   Prospective observational study.

2. **Study setting**

   This prospective Study will be carried out at our Tertiary care hospital on cases with inclusion and exclusion criteria between february 2023 to may 2025

3. **Study population**

   All male and female patients having intertrochanteric and subtrochanteric fracture with more than 18 years of age

4. **Sample Size**

   Minimum 50 patients having intertrochanteric or subtrochanteric fractures.

5. **Sampling technique**

   Simple random sampling

6. **Operational definition**

Lateral position is an approach for treating intertrochanteric and subtrochanteric fractures.

7.Methods of measurement

a) Observer technique for collecting radiological data.

b) Measurement of clinical records and associated lab values

c) To assess functional outcome by Harris Hip Score.

Study requires the following investigations.

- X-ray of the affected hip joint in anteroposterior view & lateral view.
- Complete hemogram
- Blood urea
- Serum creatinine
- Serum electrolytes
- Blood grouping and Rh typing
- Bleeding Time and Clotting Time.
- Urine routine
- Random Blood Sugar
- HIV 1 and 2
-HbsAg
- ECG

Before subjecting the patients for investigations and surgical procedures written/informed consent will be obtained from each patient/ legal guardian.

8.Data collection tools

Pre and post operative x-ray

Clinical records

9. **Methods of data collection**

i. Study site:
Department of ORTHOPAEDICS at a tertiary care teaching hospital

ii. Sample population:
All the patients coming to hospital with I/T and subtrochanteric fracture and are willing for the study.

Statistical analysis

- After data collection, data entry will be done in a Microsoft Excel sheet.
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed.

- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation.
- With the help normality assumption, we use most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant.

10. **Appropriate data management and analysis procedure**

The study is a clinical, prospective and observational study conducted at our institute. After obtaining a detailed history, complete general physical and systemic examination, the patients will be subjected to relevant investigations. The complete data will be recorded in a specially designed case recording form. The data collected will be transferred into a master chart which is subjected to statistical analysis by the biostatistician. Finally after the diagnosis, the patients are selected for the study depending on the inclusion and exclusion criteria. Post-operatively all cases will be followed up for a minimum period of 6 months.

12. **Data analysis plans and methods**

Statistical analysis of data is carried out by appropriate statistical test

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19. **Dr. Shashikant S Gadhe Pramod BhorDr. Ibad Patel** Comparative study of PFNA vs PFNA 2 in unstable intertrochanteric fractures: A randomised control study of 50 cases

TIMELINE CHART

Stages of thesis project	February 2023	March-April 2023	May-June 2023	July 2023	July 2023 - February 2025	April-May 2025
1) Selection of thesis topic	■					
2) Institutional ethics committee approval		■				
3) Review of literature			■			
4) Online submission of synopsis to MUHS				■		
5) Data collection and tabulation of records					■	
6) Compilation and analysis of data					■	
7) Write-up and final thesis submission						■

Annexure

PROFORMA

PATIENT PROFILE

1. Patient name

2. Age/sex

3. Address

4. Date of trauma

5. Side of fracture

6. Mode of injury

7. Type of fracture

8. Date of admission

9. Chief complaints

10. Signs and symptoms

11. Past history

12. Lab reports

13. Date of surgery

14. Inter operation finding

15. OT procedure

16. Post operation orders

17. Date of discharge

18. Follow up

[a]Fracture Union

[b]Movements

[c]Complication – deformity, limb length discrepancy, etc

[d]Harris hip score

Informed Consent Form

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Informed Consent Form

Name:

Age:

Sex:

Address:

Op/Ip No.:

Doctor's Name:

I, the undersigned Mr./Mrs._____, through this letter consent to voluntarily participate as a participant in the following study

"A PROSPECTIVE STUDY OF MANAGEMENT OF INTERTROCHANTERIC AND SUBTROCHANTERIC FRACTURE OF FEMUR IN LATERAL POSITION"

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

I agree that my participation in this study is voluntary.

I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.

I understand that my identity will not be revealed.

I understand that the data collected during the study might be used for further research work and publication purposes.

I have been fully explained about the implant and its complications.

I have been explained about blood transfusion if needed during procedure and its complications.

Patient's signature/thumbprint

Date:

Witness signature/thumbprint.

Relation:-

Date:-

2)Witness signature/thumbprint

Relation:-

Date:-

Doctor's Signature

Date:-

PG Guide signature

Date:-

HOD signature

Date:-

JMF's ACPM Medical College Dhule

Proforma for Submission of Synopsis to BORS

Name of the postgraduate student:

Dr.Sriram Raghavendra Kulkarni

Name of the Guide and Designation:

UNDER THE GUIDANCE OF

DR.SHAILENDRA PATIL

PROFESSOR

DEPARTMENT OF ORTHOPAEDICS

JMF'S ACPM MEDICAL COLLEGE, DHULE

Course and subject of Specialization:

M. S. ORTHOPAEDICS

Date of admission to the course:

14-01-2023

Title of the Study / Dissertation:

CLINICAL STUDY OF MANAGEMENT OF SUPRACONDYLAR FRACTURES OF FEMUR BY DIFFERENT METHODS OF SURGICAL INTERVENTION

INTRODUCTION

The femur is the largest tubular bone in the body connecting between tibia and pelvic bone. It is surrounded by the largest mass of muscles, having three portions as proximal, middle and distal third. The distal femur (supracondylar and intercondylar) comprises the distal 10 to 15 cms of the femur [1]. The supracondylar area is defined as the zone between the femoral condyles and the junction of the metaphysis with the femoral diaphysis [2]. Femur is almost cylindrical in most of its length and bowed with a forward convexity [3]. It is narrowest in the mid shaft, expands a little as it is traced upward and widens appreciably near the lower end of the bone [4]. Supracondylar fracture is known as Muller's type - A subgroup of extra-articular fractures of distal femoral fractures [5].

These fractures have got wide variety of fracture patterns and they are commonly associated with injuries such as open wounds, ligament disruption and fractures of acetabulum, femoral neck and shaft, tibia, patella etc. These serious injuries have the potential to produce significant long-term disability especially when they are associated with extensive articular cartilage damage, marked bone comminution, and severe soft tissue injury [6].

Supracondylar fractures of femur is a catastrophic event with an age and gender-related bimodal distribution and occur most frequently in young men after high energy trauma and in elderly women after a low-energy fall [1, 4]. The most common causes of such severe trauma are road traffic accidents (RTA), falls from height and gunshot injuries. The incidence is on the rise because of increasing vehicular accidents and rapid urbanization.

The management of supracondylar femoral fractures has seen a paradigm shift from non-operative measures in 1960 to biological fixation and evolution of

modern implants as well as specific techniques in current times [7]. Several methods of treatment of is now available; the choice of a particular method being determined by the type, location, degree of comminution, age of the patient, surgeon's expertise and the availability of implants and instruments. The surgical goals of treatment are anatomic reduction of the fracture, restoration of limb alignment, length, and rotation, bone grafting for extensive bone loss and stable fixation that allows for early mobilization. Metaphyseal comminution is a challenge to conventional plate fixation.

Among the operative managements, locking compression plate gives one of the best clinical results especially in highly comminuted and osteoporotic fractures where intramedullary fixation cannot be applied due to very short distal fragment.[8,9,10]

Review Of Literature:

In 1770, LAPEJODE AND SIORE first used brass wire to internally fix long bone fractures.

1933 - MAHORNER and his Colleague BRADBURN reported unsatisfactory results with Russel traction.

1937 - TEES suggested skin traction for reduction and immobilization.

1945 - FUNSTEN AND LEE observed fractures of the distal third healed earlier than that of middle or proximal third.

1948 - UNMANSKY used the reverse Blount plate for fixing the distal femoral fracture.

1951 - DELMORE, WEST and SCHRIBER suggested fibrosis or arthro fibrosis after trauma as the prime cause of knee stiffness.

1953 - LAING P.G studied the blood supply and concluded no major vessels entering distal femur and the abundant blood supply was through genicular vessels and soft tissue attachments.

1955 - WATSON - JONES recommended non operative treatment.

1963 - SIR JOHN CHARNLEY recommended non operative treatment.

1965 - MULLER suggested L shaped compression plate (ASIF condylar plate) and suggested postero lateral incision.

1966, MARCUS J. STEWART, SISK and WALLACE retrospectively reviewed 213 cases of supracondylar and inter condylar femur fractures and recommended, two pin traction as the treatment of choice.

1967 - NEER – classified the supracondylar fractures of femur and advised conservative management[11,12]

1971 - BROWN & DARCY modified blade plate for use in osteoporotic supracondylar fractures.

1972-OLERUD in his study shows 93% good results in fractures treated with condylar buttress plates, but the procedure was technically demanding with high rate of implant failure which resulted in re fracture after implant removal. The failure rate was high especially in osteoporotic bone.

1973 - CONNOLY advocated closed reduction and cast brace ambulation. 1974 - SCHATZKER reported superior results using operative methods3. 1974 - NEER – classified supracondylar / inter condylar fractures, used straight plate and screws and considered conservative treatment was superior to internal fixation.

1979 - SCHATZKER J - concluded that results of blade plate fixation were better.

1980 - FRANK SEINSHEIMER - classified distal femoral fractures and advocated fixation for intra articular fractures.

1984 - SWIONTKOWSI et al. described retrograde intramedullary nailing though insertion in the medial femoral condyle which is in line with the center of the femoral shaft in the coronal plane.

1984 - AO/ASIF Universal tibial and femoral nails were used with entry point in the medial femoral condyle.

In 1986 REGAZONNI, RUEDI and ALLGOWER used the Dynamic condylar screw implant system for fractures of the supracondylar fracture femur, but the main disadvantage of condylar screw implant was that the fixation of condylar lag screw results in removal of a large amount of bone which made redo surgery more difficult and varus collapse of the distal fragment was a recognized complication.

1990 - MULLER classified fracture of distal femur (AO classification)

1991 - MARK S BULTER et al. used interlocking intramedullary nailing for ipsilateral fractures of the femoral shaft and distal part of femur.

1991 - GREEN S, SELIGSON D, HENRY SL, TRAGER S primarily used GSH Supracondylar nail (retrograde interlocking nailing)

1991-SANDERS. R., SWIONTKOWSKI, used double plating for comminuted, unstable fractures of distal femur.

In 2000, LCP was approved as new AO plate standard

In 2001 KREGOR P.J. STANNARD J., ZLOWODZKI. M. reported early results with L.I.S.S for distal femoral features.

In 2003 FRIGG. R. published an article about the “Development of the locking compression plate”.

In 2003 SOMMER C, GAUTIERE, MULLER M, HELFET DL,WAGNER reported first clinical results of the locking compression plate.

In 2005 SEAN E. WORK, DANIEL N., studied association between supracondylar- Intercondylar distal femur fractures and coronal plane fractures.

In 2006 HEATHER A., VALLIER reported failure of LCP condylar plate fixation in the distal part of the femur in selected cases.

Primary Objective

To analyze clinical and functional outcome of patients with supracondylar femur fracture treated by Locking compression plating and Retrograde Supracondylar nailing.

Other Objective 1

To evaluate the benefits of Locking compression plating over Retrograde Supracondylar Nailing for management of Supracondylar Femur fracture.

Other Objective 2

To analyze the complications following surgery

Research Questions:

Primary Research Question:

What is the functional outcome and result of surgical management of supracondylar femur fracture?

Secondary Research Question:

Nil

AIMS & OBJECTIVES

Aim:

The aim of the study is to analyse prospectively the results of Locking compression plating and Retrograde Supracondylar Nailing in the management of Supracondylar Femur Fractures.

Objectives:

1. To assess the stability of fixation and early mobilization of patients.
2. To evaluate the benefits of Locking compression plating and Retrograde Supracondylar Nailing for management of Supracondylar Femur fracture.
3. To study postoperative complications.

MATERIALS AND METHODS

Study Design: Prospective observational study.

Study site: This study will be conducted in tertiary care hospital.

Study Population: All male and female patients having supracondylar femur fractures above 18 years of age

Study setting: This prospective study will be carried out at our tertiary care hospital on cases with inclusion and exclusion criteria between 2023 to 2025

Study Period: Two year

Study duration:2023-2025

Following inclusion and exclusion criteria will be used.

Inclusion criteria:

1. Patient who has been diagnosed as having supracondylar femur fractures.

2. Patients with more than 18 years of age
3. Patient who are fit for surgery.

Exclusion criteria:

1. Patients with pathological fractures.
2. Patients with less than 18 year's of age
3. Polytrauma Patients
4. Patient not willing for surgery
5. Patients unfit for surgery

Method of collection of data

- By interview
- By follow up at intervals of 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- By clinical examination
- By analysing case papers,Preoperative and Postoperative Xrays

Patients admitted with Supracondylar femur fracture will be examined and investigated with X-ray Both Knee joints AP and Lateral view (whenever possible).Mid Tibial Pin Traction will be applied in all cases.

Outcome measurement:

- All patients will be followed up in clinic at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.
- Pain will be assessed on Visual Analogue Scale.
- Radiographic measurements will be done by two orthopedic traumatologists. Antero-posterior (AP) and lateral radiographs (Lat) assessed by PACS software were used for quality of fracture reduction,

- Osseous healing was designated radiologically as presence of atleast three of the four cortices with bridging callus formation and crossing Trabeculae in AP And Lateral radiographs.
- The primary outcome will be measured by time to union (weeks), functional outcome (Oxford Knee Score), any medical complications including Venous Thromboembolism (VTE), surgical complication, and mortality.

Methodology

1. **Study design**

   Prospective observational study.

2. **Study setting**

   This prospective Study will be carried out at our Tertiary care hospital on cases with inclusion and exclusion criteria between 2023 to 2025

3. **Study population**

   All male and female patients having supracondylar femur fracture with more than 18 years of age

4. **Sample Size**

   Minimum 45 patients having supracondylar femur fractures.

5. **Sampling technique**

   Simple random sampling

6. **Operational definition**

Locking compression plating and Retrograde Supracondylar Nailing are modalities for treating Supracondylar Femur fractures.

7.Methods of measurement

a) Observer technique for collecting radiological data.

b) Measurement of clinical records and associated lab values

c) To assess functional outcome by Oxford Knee Score.

Study requires the following investigations.

- X-ray of the affected Knee Joint in anteroposterior view & lateral view.
- Complete hemogram
- Blood urea
- Serum creatinine
- Serum electrolytes
- Blood grouping and Rh typing
- Bleeding Time and Clotting Time.
- Urine routine
- Random Blood Sugar
- HIV 1 and 2
-HbsAg
- ECG

Before subjecting the patients for investigations and surgical procedures written/informed consent will be obtained from each patient/ legal guardian.

8.Data collection tools

Pre and post operative x-ray

Clinical records

9. **Methods of data collection**

i. Study site:
Department of ORTHOPAEDICS at a tertiary care teaching hospital

ii. Sample population:
All the patients coming to hospital with Supracondylar femur fractures and are willing for the study.

iii. **Sample size calculation**:

According to the https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5721335/

The sample size was calculated using the formula:

$n = Z^2 P (1 - P)/ d^2$,

where Z is the critical value of the Normal distribution (for a confidence level of 95%, the critical value is 1.96),

P = prevalence of 3

d is the margin of error, which is considered 5 for the study

Based on the above parameters, the sample size calculated is:

Minimum sample size for the study per group = 45 & above

Statistical analysis

- After data collection, data entry will be done in a Microsoft Excel sheet.
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed
- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation.
- With the help normality assumption, we use most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant.

10. **Appropriate data management and analysis procedure**

The study is a clinical, prospective and observational study conducted at our institute. After obtaining a detailed history, complete general physical and systemic examination, the patients will be subjected to relevant investigations. The complete data will be recorded in a specially designed case recording form. The data collected will be transferred into a master chart which is subjected to statistical analysis by the biostatistician. Finally after the diagnosis, the patients are selected for the study depending on the inclusion and exclusion criteria. Post-operatively all cases will be followed up for a minimum period of 6 months.

12. **Data analysis plans and methods**

Statistical analysis of data is carried out by appropriate statistical test

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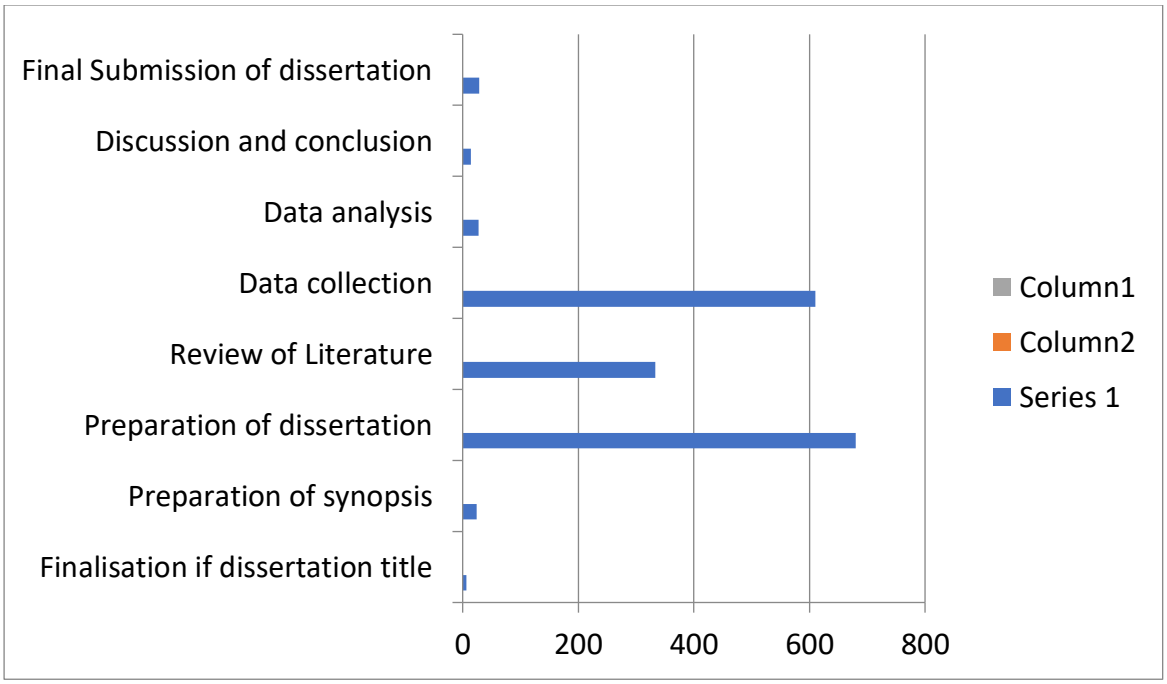
TIME LINE CHART

Task name	Start date	End date	Duration
Finalisation of dissertation title	01/02/2023	15/02/2023	15days
Preparation of synopsis	16/07/2023	02/04/2023	46days
Preparation of dissertation	12/05/2023	21/03/2025	680days
Review of Literature	12/05/2023	08/04/2024	333days
Data Collection	12/06/2023	10/02/2025	610days
Data analysis	14/01/2025	10/02/2025	28days
Data presentation	11/02/2025	24/02/2025	14days
Discussion and conclusion	25/02/2025	10/03/2025	14days
Submission of dissertation	11/03/2025	09/04/2025	30days
Final submission of dissertation	10/04/2025	08/05/2025	29days
Total duration	**01/02/2023**	**08/05/2025**	**828 days**



Annexure

PROFORMA

PATIENT PROFILE

1. Patient name

2. Age/sex

3. Address

4. Date of trauma

5. Side of fracture

6. Mode of injury

7. Type of fracture

8. Date of admission

9. Chief complaints

10. Signs and symptoms

11. Past history

12. Lab reports

13. Date of surgery

14. Inter operation finding

15. OT procedure

16. Post operation orders

17. Date of discharge

18. Follow up

[a]Fracture Union

[b]Movements

[c]Complication – deformity, limb length discrepancy, etc

[d]Oxford Knee Score

Informed Consent Form

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Informed Consent Form

Name:

Age:

Sex:

Address:

Op/Ip No.:

Doctor's Name:

I, the undersigned Mr./Mrs._____, through this letter consent to voluntarily participate as a participant in the following study

"CLINICAL STUDY OF MANAGEMENT OF SUPRACONDYLAR FRACTURES OF FEMUR BY DIFFERENT METHODS OF SURGICAL INTERVENTION"

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

I agree that my participation in this study is voluntary.

I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.

I understand that my identity will not be revealed.

I understand that the data collected during the study might be used for further research work and publication purposes.

I have fully explained about locking compression plate implant and its complications.

I have explained about blood transfusion if needed during procedure and its complications

Patient's signature/thumbprint

Date:

1) Witness signature/thumbprint.

Relation:-

Date:-

2)Witness signature/thumbprint

Relation:-

Date:-

Doctor's Signature

Date:-

PG Guide signature

Date:-

HOD signature

Date:-

Proforma for Submission of Synopsis to BORS

1 **Name of the postgraduate student:**

Dr. Dahake Pankaj Narendrakumar

2 **Name of the Guide and Designation:**

Dr. Dilip Patil MBBS (MD MEDICINE)

3 **Course and subject of Specialization**

MD MEDICINE (3 year)

4 **Date of admission to the course**:2-5-2022

5 **Title of the Study / Dissertation:**

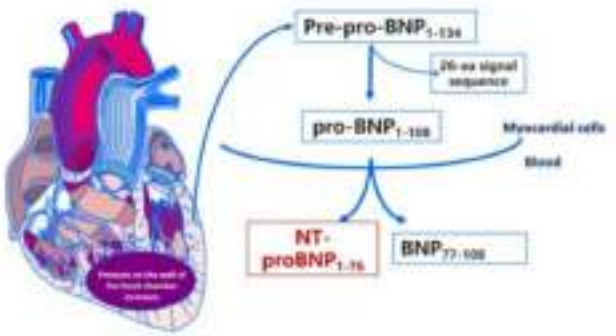
Clinical study of acute myocardial infarction with special reference to N-Terminal pro Brain Natriuretic Peptide on admission.

6 Brief Resume of the intended work

INTRODUCTION :

Cardiovascular Diseases (CVDs) represent 31% of the world mortality rate, according to the World Health Organization, with an estimated 17.9 million deaths per year .CVDs are associated with numerous non-modifiable risk factors such as age, sex, race, and family genetics and modifiable, such as unbalanced diet, alcoholism, smoking, stress, and sedentary lifestyle . The CVDs include coronary heart disease (such as acute coronary syndromes and heart failure), cerebrovascular disease, rheumatic heart disease and other conditions. Among the acute coronary syndromes, Acute Myocardial Infarction (AMI) is classified as one of the main causes of hospitalizations and deaths in the world(1)

Cardic biomarkers are biological macromolecules that can be used in laboratory routine and clinical as confirmatory evidence for diagnostic of the Acute Myocardial Infarction (AMI). Several cardiac biomarkers, such as cardiac enzymes and especific cardio proteins, have been traditionally used in the AMI diagnostic. However, the difference between the sensitivity and specificity of the biomarker of clinical choice can be assistance of in the early diagnosis and the evaluation prognosis of the infarcted patient. The purpose of this review is to summarize an update of the clinical cardic biomarker used in the diagnostic of AMI, specifying the criterion of sensitivity, tissue performance and its correlation regarding the diagnosis.(1)



During the last decade, B type-natriuretic peptides have moved on from bench to bedside very quickly. Originally, they were introduced in clinical practice as a diagnostic tool for heart failure (HF) (1). Later, their independent prognostic value was also shown, especially concerning mortality and heart failure, in patients with stable and unstable coronary artery disease (CAD) (2–5). On the other hand, data about acute coronary events prediction are still conflicting; in contrast to the PEACE trial (in which neither BNP nor NT-proBNP significantly increased the risk of myocardial infarction (MI), The Heart and Soul Study found an independent association of both markers with the individual outcomes of heart failure, myocardial infarction and cardiovascular death . Also, NT-proBNP was found to be a useful biomarker for distinguishing patients with long-standing hypertension who are at risk of heart failure, allowing optimization and proper treatment of these patients (2)

Patients with previous myocardial infarction represent a heterogenous group, whose prognosis differs significantly. Since traditional risk factors have less prognostic value in this secondary prevention population, they are important candidates for neurohumoral testing. Serial analyses of NT-proBNP in patients with non-ST segment elevation acute coronary syndromes (FRISC-II substudy) showed that levels measured during a chronic, relatively stable phase are a better predictor of mortality than those measured during an acute, unstable phase . Also, assessment of NT-proBNP level 6 months after ST-elevation MI was a better indicator of infarct size and left ventricular function measured by cardiac magnetic resonance than baseline (admission) NT-pro BNP values (2)

Although previously thought to be equally effective for diagnostic and prognostic purposes , recently published data from »The Heart and Soul Study« found NT-proBNP to be superior to BNP, when added to clinical risk factors, for net reclassification of the risk for major adverse cardiac events in patients with stable CAD .(2)

Meta-analysis of nine prospective studies, which indicated strong association between the circulating concentration of NT-proBNP and long-term prognosis of patients with stable CAD, pointed out that although most of the included studies grouped the population according to the median or quartiles of NT-proBNP, the specific NT-proBNP, levels varied greatly among different studies, making it impossible to give a precise cut-point .(2)

N-terminal pro-brain natriuretic peptide (NT-proBNP [1–76]) represents the N-terminal fragment of proBNP (1–108), the high-molecular-weight precursor of functionally active BNP. The major source of NT-proBNP and BNP is the cardiac myocyte. In these cells, NT-proBNP is cleaved from the precursor

and secreted in equimolar amounts, together with BNP. NT-proBNP circulates at considerable concentrations in human plasma, can easily be detected and quantified by immunometric assay,1,2 and is stable in whole blood.2,3 ProBNP synthesis is activated during mechanic and neurohumoral stimulation of the heart,4–7 and the high secretion rate of BNP from hypertrophied and failing ventricles8,9 results in a close correlation between BNP and left ventricular (LV) systolic dysfunction10–13 and hypertrophy.14

Recent studies have demonstrated elevated NT-proBNP concentrations in experimental LV dysfunction15 and after acute myocardial infarction (MI).16,17 No information is currently available regarding the usefulne
ss of NT-proBNP as a biochemical marker of LV dysfunction in outpatients. Furthermore, no other parameters that might affect the association between LV dysfunction and NT-proBNP have been investigated in larger samples.(3)

7.1 Need for the study:

Today the most frequent cause of the failing heart is coronary artery disease- acute myocardial infarction. In this work we wanted to observe NT- proBNP release in acute myocardial infarction and investigate its correlation with the left ventricle ejection fraction, left ventricle dimension and peak value of troponin, localization of infarction, modus of therapy and survival. There are only few studies about BNP release in AMI, still precise mechanism for it secretion has not been clear. In today reports have been many controversies and conflicts (2)

RESEARCH QUESTION

PRIMARY RESEARCH QUESTION:

What is the significance of NTproBNP level on admission in Acute Myocardial Infarction?

SECONDARY RESEARCH QUESTION-

What's the significance of NTproBNP level with Heart FailurE.

7.2 Review of Literature:

Since serial analyses of NT-proBNP in patients with acute coronary syndromes have shown that levels measured during a chronic, later phase are a better predictor of prognosis and indicator of left ventricular function than the levels measured during an acute phase, we sought to assess the association of NT-proBNP, measured 6 months after acute myocardial infarction (AMI), with traditional risk factors, characteristics of in-hospital and early postinfarction course, as well as its prognostic

value and optimal cut-points in the ensuing 1-year follow-up.[1]

B-type natriuretic peptide is released from the cardiac ventricles in response to increased wall tension.[2]

The BNP and NT-proBNP levels were strongly related to the incidence of cardiovascular mortality, heart failure, and stroke but not to myocardial infarction. In multivariable models, BNP remained associated with increased risk of heart failure, whereas NT-proBNP remained associated with increased risk of cardiovascular mortality, heart failure, and stroke. By C-statistic calculations, BNP and NT-proBNP significantly improved the predictive accuracy of the best available model for incident heart failure, and NT-proBNP also improved the model for cardiovascular death. The magnitude of effect of ACE inhibition on the likelihood of experiencing cardiovascular end points was similar, regardless of either BNP or NT-proBNP baseline concentrations. [3]

The base-line level of B-type natriuretic peptide was correlated with the risk of death, heart failure, and myocardial infarction at 30 days and 10 months. The unadjusted rate of death increased in a stepwise fashion among patients in increasing quartiles of base-line B-type natriuretic peptide levels (P<0.001).[4]

Patients with hypertensive heart disease have elevated concentrations of N-terminal pro-B-type natriuretic peptide (NT-proBNP). The aim of our study was to evaluate NT-proBNP in patients with long-standing hypertension and in patients with signs of hypertensive cardiomyopathy. [5]
Background Brain-type natriuretic peptide (BNP) and the amino-terminal fragment of its prohormone (NT-pro BNP) are known predictors of cardiovascular outcomes in patients with coronary heart disease; however, the relative prognostic value of these 2 biomarkers for secondary events remains unclear.[6]

Aim of the study was to evaluate the utility of N-terminal pro-B-type natriuretic peptide (NT-pro BNP, pg/ml) assessment to predict infarct size and left ventricle function after ST-segment elevation myocardial infarction (STEMI) at long-term follow-up.[7]
Brain natriuretic peptide and NTproBNP correlated closely (r 0.90, p 0.001) and had similar relationships to LVEF (r 0.50 and 0.46, respectively, both p 0.001), age (0.44 and 0.47, both p 0.001), and creatinine clearance (0.51 and 0.51, both p 0.001). Areas under receiver-operating characteristic curves for detection of LVEF 30% were similar (0.83 and 0.80, both p 0.001) with strong negative predictive values for both (95% and 94%). Both markers independently predicted the clinical end point with closely overlapping event-free survival curves.[8]

A detailed process of the study selection is shown in Figure 1. Among the 13 potentially relevant N-terminal prohormone B-type natriuretic peptide (NT-proBNP) is a stable fragment of the B-type natriuretic peptide (BNP) precursor, which is a neurohormone synthesized and released primarily from the cardiac ventricles in response to increased ventricular stretch and wall tension. Measurement of circulating levels of NT-proBNP has been recommended in the diagnosis and prognosis of patients with heart failure.1 NT-proBNP was also documented, by in

vitro study, to be directly released from cardiomyocytes in response to myocardial ischemia.2

Therefore, it has been proposed that measurement of their circulating levels can be used for stratification of cardiovascular risk in populations with ischemic heart disease. In recent years, many clinical studies have investigated the relationship between concentrations of NT-proBNP and the subsequent risk of patients with stable coronary artery disease (CAD); most of them have not been systematically assessed. One previous metaanalysis reviewed the relationship between BNP/NT-proBNP and cardiovascular risk in general populations or in those at high risk for CAD, but not in patients with stable CAD and a clear diagnosis.3 We also noticed that, in most relevant studies addressing NT-proBNP and stable CAD, the study populations were divided into four quartile groups according to NT-proBNP concentrations and the clinical outcomes of different groups were reported, respectively.

Thus, sufficient data were available to reanalyze the prognosis in patients with different NT-proBNP …many clinical studies have investigated the relationship between concentrations of NT-proBNP and the subsequent risk of patients with stable coronary artery disease… Vol. 14 No. 2-4 • 2013 • Reviews in Cardiovascular Medicine • e93 N-terminal ProBNP and Stable Coronary Artery Disease was 1.33 (95% CI, 0.83-1.82) for the second versus the first quartile. In the comparison between the third and fourth versus the first quartile, the HRs were 1.85 (95% CI, 1.23- 2.48) and 2.74 (95% CI, 1.85-3.62), respectively (Figure 2). The risk of developing unfavorable clinical events increased significantly with each increasing quartile of baseline NT-proBNP concentration. No considerable heterogeneity among the six available studies was found [9]

In a multiple logistic regression model, NT-proBNP above the upper normal limit (125 pg/mL) predicted clinically significant coronary disease at angiography independently of traditional cardiovascular risk factors and invasive measurements of left ventricular function (odds ratio 2.1, 95% CI 1.3-3.2, P = .001). The ability of NT-proBNP in detecting clinically significant coronary disease at angiography was modest, however, with sensitivity of 0.61, specificity 0.60, accuracy 61 (95% CI 58-64), positive likelihood ratio 1.5 (95% CI 1.3-1.8), negative likelihood ratio 0.7 (95% CI 0.6-0.8), and area under the ROC curve 0.61 (95% CI 0.58-0.64).[10]

Among 798 participants (84.7% men, mean age 59 years) there were 114 adverse cardiovascular events. 12-months NT-proBNP levels were higher than baseline levels in 60 patients (7.5%) and numerically more strongly associated with the outcome in multivariable analysis (HR 1.65 [95% CI 1.33–2.05] vs. HR 1.41 [95% CI 1.12–1.78], with a net reclassification improvement (NRI) of 0.098 [95% CI 0.002–0.194] compared to NRI of 0.047 [95% CI −0.0004–0.133] for baseline NT-proBNP levels. A 12-month 10% increment of NT-proBNP was associated with a HR of 1.35 [95% CI 1.12–1.63] for the onset of an adverse cardiovascular event. Subjects with a 12-month increment of NT-proBNP had a HR of 2.56 [95% CI 1.10–5.95] compared to those with the highest 12-months reduction.[11]

To study the effect of acute myocardial hypoxia on cardiac BNP expression, we used a new

porcine model with low oxygen delivery to the left ventricular myocardium. Myocardial hypoxia rather than anoxia was achieved by ligation of the left anterior descending interventricular artery and partial restoration of the blood flow through a myocardial vein. The oxygen tension in the affected porcine myocardium was similar to that in patients with chronic ischemic heart disease (36,40). The experimental model therefore allowed us to study the BNP gene and peptide expression in both normoxic and hypoxic myocardium from the same ventricle, thus minimizing possible biases from anesthesia or neurohormonal activation during surgery.[12]
—Although levels of various inflammatory biomarkers are significantly related to future cardiovascular risk, their incremental predictive value is modest. A model consisting of simple traditional risk factors and Nt-proBNP provided the best clinical prediction in the secondary-prevention population.[13]

HYPOTHESIS

PRIMARY HYPOTHESIS:

Level of NT pro-BNP Increase in Acute Myocardial Infarction.

SECONDARY HYPOTHESIS:

Level of NT pro-BNP as a prognostic marker for heart failure in Acute Myocardial Infarction

Aims and Objectives:

Clinical study of acute Myocardial infarction with special reference to NT- proBNP on admission.

PRIMARY OBJECTIVE:

To Evaluate the co-relation between NTproBNp level and Acute Myocardial infarction.

OTHER OBJECTIVE:

To Evaluate the values of NTproBNP level as the early prognostic Marker for Heart Failure in Acute Myocardial infarction.

MATERIAL AND METHODS

Study site: Department of Medicine at a tertiary care teaching hospital

Sample population: All the patients coming to hospital and for the study of acute myocardial infarction with special reference to NT- proBNP on admission.

Sample size calculation:

According to the article:

Risk factors for acute myocardial infarction in coastal region of india: A case-control study.[14]

The Prevalence is 6.43%

The sample size was calculated using the formula:

$n = Z^2 P (1-P)/d^2$

where Z is the critical value of the Normal distribution (for a confidence level of 95%, the critical value is 1.96).

P = prevalence of 6.43 %

d is the margin of error, which is considered 7.5% for the study

Based on the above parameters, the sample size calculated is:

Minimum sample size for the study per group is 42 patients and above

Statistical analysis

- After data collection, data entry will be done in a Microsoft Excel short
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed
- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation
- With the help normality assumption, we most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant

Source of data:
JMF's ACPM MEDICAL COLLEGE, DHULE

Type of study:

Prospective ,Descriptive type of Observational Study

Sampling Technique:

Convenient Sampling

In-vitro/in-vivo/survey:

In vivo

Source from where the cases, patients, subjects or study material will be selected:

ICU, IPD and Casualty patients of ACPM Medical college and hospital Dhule Maharashtra.

Name and place where the study will be conducted:

ACPM Medical college and hospital Dhule Maharashtra.

Inclusion criteria:

1. Adults > 18 years
2. All the patients in which symptoms of Acute Myocardial Infarction.
3. ECG changes Suggestive of Acute Myocardial Infarction.
4. Patients with evidence of Acute Myocardial infarction more than 18 yrs of age
5. Patients in whom these test is prescribed by practising physician and Patient willing to give informed consent

Exclusion criteria:

1. Pregnant Ladies
2. Pericardial Effusion
3. Cardiomyopathies
4. Hyperthyroidism

The materials/instruments/armamentarium to be used in the study:

NT Pro BNP Testing kite
IPD patients record
statistical studies
Bar Graph

Procedure:

The blood samples for NT- proBNP analysis in AMI group were taken within first 48 hours from the

beginning of the symptoms. BNP was determinated with from venous blood collected in EDTA plastic tubes (Ethylenediaminetetraacetic acid).

Duration of study

Period of 2 years 2022 – 2024 covering 42 and above patients analysis.

Does the study require any investigation or intervention to be made on patients, any human or animals?

Yes - NT - proBNP Investigation

List of References

1

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3. Omland, T. *et al.* Prognostic Value of B-Type Natriuretic Peptides in Patients With Stable Coronary Artery Disease. The PEACE Trial. *J Am Coll Cardiol* **50**, 205–214 (2007).
4. Ames, J. *et al. THE PROGNOSTIC VALUE OF B-TYPE NATRIURETIC PEPTIDE IN PATIENTS WITH ACUTE CORONARY SYNDROMES A BSTRACT Background Brain (B-type) natriuretic peptide is a*. *N Engl J Med* vol. 345 www.nejm.org (2001).
5. Pejović, J., Ignjatović, S., Dajak, M., Majkić-Singh, N. & Vučinić, Ž. N-terminal pro-B-type natriuretic peptide in patients with hypertensive heart disease. *J Med Biochem* **30**, 244–249 (2011).
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patients with coronary heart disease. *PLoS One* **10**, (2015).
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14. Vinay Rao, Prasannalakshmi Rao, Nikita Carvalho. **Risk factors for acute myocardial infarction in coastal region of india: A case-control study**

16) TIMELINE CHART:

Stages of Research Project	**June 2022**	**July 2022**	**Aug 2022-Oct 2022**	**Nov 2022 – March 2024**	**April 2024-June 2024**	**July 2024 – Sept 2024**
1). Literature search for research topic						

2). Selection of thesis topic						
3). Institutional ethical committee						
4). Online submission of title and synopsis of dissertation to MUHS						
5). Data collection and tabulation of records						
6). Compilation and analysis of data						
7). Write-up and final submission						

17) ANNEXURES:

PROFORMA

Basic information

Patients Age : _____ Date: _____ _____

Sex/Age : _____

Occupation : _____ _____

Symptoms and Duration : _____

Past History: _____

Family History: _____

_____

General Examination:

P-
BP-
SpO2-
Pallor- Y/N
Clubbing- Y/N
Icterus- Y/N
Lymphadenopathy-Y/N
Oedema-Y/N

CNS

CVS

RS

Systemic Examination:

PA

सहमति पत्र

मैं " (NT pro BNP) स्तर के विशेष संदर्भ के साथ पुरानी गुर्दे की विफलता का मूल्यांकन" नामक शोध अध्ययन के मामलों में से एक के रूप में भाग लेने के लिए तैयार हूं।

2. मुझे इस शोध अध्ययन के बारे में ऑडियो-विजुअल माध्यमों से विस्तार से जानकारी दी गई है।
3. मुझे विभिन्न जटिलताओं के बारे में भी बताया गया है; चिकित्सा या तकनीकी, अस्थायी या स्थायी, तत्काल या दीर्घकालिक आदि जो इस अध्ययन के दौरान उत्पन्न हो सकते हैं और उन्हें अध्ययन के संबंध में प्रश्न पूछने की अनुमति दी गई है।
4. यह मुझे मेरी समझ की भाषा में समझाया गया है।
5. सभी जानकारी को समझने के बाद, मैं बिना किसी बल या जबरदस्ती के इस सहमति पत्र पर हस्ताक्षर कर रहा हूं।

रोगी/रिश्तेदार/साथी के हस्ताक्षर
दिनांक:
गवाह के हस्ताक्षर:-
दिना

संमती पत्र

“NT pro BNP ” या शीर्षकाच्या संशोधन अभ्यासासाठी मी एक प्रकरण म्हणून भाग घेण्यास इच्छुक आहे.

2. मला या संशोधन अभ्यासाबाबत दृकश्राव्य माध्यमातून सविस्तर माहिती देण्यात आली आहे.

3. मला विविध गुंतागुंतांबद्दल देखील माहिती देण्यात आली आहे; वैद्यकीय किंवा तांत्रिक, तात्पुरते किंवा कायम, तात्काळ किंवा दीर्घकालीन इत्यादी जे या अभ्यासादरम्यान उद्भवू शकतात आणि त्यांना अभ्यासासंबंधी प्रश्न विचारण्याची परवानगी दिली आहे.
4. हे मला माझ्या समजुतीच्या भाषेत समजावून सांगितले आहे.
5. सर्व माहिती समजून घेतल्यानंतर, मी या संमतीपत्रावर कोणतीही सक्ती किंवा जबरदस्ती न करता स्वाक्षरी करत आहे.

रुग्ण/नातेवाईक/सहकारी यांची स्वाक्षरी
तारीख:
साक्षीदाराची स्वाक्षरी:-
तारीख:

Informed Consent Form

Name: Age:

Sex: Address:

ODD/IPD No. :

Doctor's Name:

I, the undersigned Mr./Mrs._____

Through this letter consent to voluntarily participate as a participant in the following study

Clinical study of acute myocardial infarction with special reference to NT- proBNP on admission.

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

- I agree that my participation in this study is voluntary.
- I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.
- I understand that my identity will not be revealed.
- I understand that the data collected during the study might be used for further research work and publication purposes.
- I have fully explained about the disease and its complications.
- I have explained about the investigations if needed during the entire process.

Patient's Signature/ Thumbprint

Date:

1] Witness Signature / Thumbprint 2] Witness Signature/ Thumbprint

Relation:

Date:

Relation:

Date:

Doctor’s Signature:

Date:

PG Guide signature

Date:

HOD Signature

Date:

Proforma for Submission of Synopsis to BORS

Name of the postgraduate student:

Dr. Viraj Eknath Chandanshive

Name of the Guide and Designation:

Dr. Puneet Patil

MD (MEDICINE)

Associate Professor

Dept. of General Medicine

JMF's ACPM Medical College Dhule

Course and subject of Specialization:

MD Medicine

Date of admission to the course:

25 April 2022

Title of the Study / Dissertation:

TO STUDY 2D ECHO EVALUATION IN TYPE 2 DIABETES MELLITUS PATIENTS (WITHOUT CARDIOVASCULAR SYMPTOMS AND WITHOUT HYPERTENSION) WITH SPECIAL REFERENCE TO DIASTOLIC FUNCTION

INTRODUCTION

Type 2 diabetes (T2DM) is a major public health problem worldwide. It is estimated that 366 million people will be affected by T2DM till the year of 2030.[1,2]

Patients with diabetes mellitus commonly develop various chronic vascular complications, including macrovascular diseases (heart disease, stroke and peripheral vascular disease) and microvascular diseases (retinopathy, neuropathy and nephropathy).[3]

The inflammatory process plays a crucial role in the pathogenesis of type 2 diabetes and precedes the onset of the disease. There is evidence that chronic inflammation may contribute to both development and acceleration of microangiopathy and macroangiopathy in diabetic patients. [4]

Premature atherosclerosis due to endothelial function, vascular effects of advanced glycation products, untoward effects of circulating free fatty acids and increased systemic inflammation is seen with diabetes.[5] This results into coronary artery disease, heart failure or arrhythmias due to diabetic cardiomyopathy. Most diabetic cardiovascular diseases are asymptomatic (silent or painless ischemia) due to autonomic neuropathy. Many patients with left ventricular function remain undiagnosed and untreated until advanced disease causes disability or death. This is the biggest challenge for primary physicians. This delay can be avoided if screening techniques are used to identify left ventricular function in its preclinical phase. [5]

A number of studies have reported a high prevalence of pre-clinical diastolic function among subjects with DM.[6] Diabetes mellitus is one of the major risk factors for diastolic heart failure (DHF). The mortality rates among the

patients with DHF ranges from 5-8% annually as compared with 10-15% among patients with systolic heart failure.[7] The evidence suggests that myocardial damage in diabetic patients affects diastolic function before the systolic function. The pathogenesis of this left ventricular (LV) function in diabetic patients is not clearly understood. It has been proposed that diabetic cardiomyopathy is an independent cardiovascular disease and many underlying mechanisms, such as microvascular disease, autonomic function, metabolic disorders, and interstitial fibrosis, have been suggested as aetiological factors.[8] Left ventricular diastolic function (LVDD) represents the first stage of diabetic cardiomyopathy preceding changes in systolic function, reinforcing the importance of early evaluation of ventricular function in individuals with diabetes. [9,10] The diastolic abnormalities are present in diabetic patients in absence of diabetic complications of cardiovascular system. [11-13]

This study will be aimed to study 2D echo evaluation in Type 2 DM patients (without cardiovascular symptoms and without hypertension) with special reference to diastolic function.

- **PRIMARY RESEARCH QUESTION**
- To study 2D ECHO Evaluation in Type 2 DM Patients (without Cardiovascular Symptoms and Without Hypertension) with Special Reference to Diastolic Function
- **SECONDARY RESEARCH QUESTION**
- Correlation of Grades of Diastolic Function on 2D ECHO with Type 2 DM

- **PRIMARY HYPOTHESIS:**

2D ECHO Findings shows that Type 2 DM is the strongest independent Factor for Structural and Functional abnormalities in Diastolic Function

REVIEW OF LITERATURE

Chawla A et al The pathologic hallmark of DM involves the vasculature leading to both microvascular and macrovascular complications.[2] Chronicity of hyperglycemia is associated with long-term damage and failure of various organ systems mainly affecting the eyes, nerves, kidneys, and the heart.[3]

Kazik A, Wilczek K, Poloski L. et al Our study indicates that myocardial damage in patients with diabetes affects diastolic function before systolic function and higher HbA1C level is strongly associated with presence of LVDD. Patients should be advised strict control of diabetes in order to reduce the risk for developing LVDD which is a precursor for more advanced disease.[6]

Piccini JP, Klein L, Georghiade M, Bonow RO et al Approximately 40% of patients with heart failure have preserved left ventricular systolic dysfunction, thus exhibiting diastolic heart failure.. Recent studies found that diabetes mellitus produces functional, biochemical, and morphologic myocardial abnormalities independent of coronary atherosclerosis and hypertension. These abnormalities may result in impaired left ventricular diastolic function, contributing importantly to heart failure with normal systolic function. [7]

AM, Scott CG, Chen HH et al Several studies have demonstrated evidence for preclinical left ventricular (LV) diastolic dysfunction in patients with diabetes mellitus (DM) independent of coronary disease or hypertension. The objectives of our study were to determine if LV diastolic dysfunction determined by tissue

Doppler indexes worsens with duration of DM and to quantify severity of function as a function of DM duration. In conclusion, duration of DM of ≥4 years is correlated with significant LV diastolic dysfunction. LV diastolic dysfunction is predictive of all-cause mortality in patients with DM independent of hypertension and coronary disease.[8]

Mamatha B Patil,Nishkal Prabhu A Burji et al Diastolic dysfunction was present in 32 (64 %) of the patients. Diastolic dysfunction was more common among female sex (68.18%) compared to male (60.17%).Diastolic dysfunction was significantly associated with uncontrolled diabetes as assessed by HbA1c levels. Diastolic dysfunction was more common in patients who were on treatment with both oral hypoglycemic agents and insulin. The prevalence of diastolic function increased with longer duration of diabetes. There was a linear progression of diastolic dysfunction with the increase age group.[11]

Patil MB, Burji Nishkal Prabhu et al The findings in our study indicate that myo cardial damage in patients with diabetes affects diastolic function before systolic function, E/A ratio; Left atrial sizes are significantly altered in diabetic patients with diastolic function. Diabetic function is significantly associated with duration of disease, glycemic control. Doppler Echo is simple, non – invasive and reproducible. It identifies large percentage of diabetic subjects who have asymptomatic left ventricular function before abnormalities are detected with ECG or by clinical examination. Therefore by early detection we can start early treatment and can retard the progression of LV diastolic function.[12]

Vanninen E, Pitale SU et al Although patients with type 2 diabetes demonstrate cardiac diastolic dysfunction, it is well known that cardiac diastolic dysfunction is produced by hypertension and aging. The purpose of the present study was to elucidate the cardiac structure and function in normotensive patients with type 2 diabetes in various age strata in order to assess the effect of diabetes mellitus itself on cardiac function. These results indicate that cardiac diastolic dysfunction without LV systolic function in

patients with well-controlled type 2 diabetes is related neither to hypertension nor LV hypertrophy, but rather to aging and the duration of type 2 diabetes.[13]

Sardesai VV, Kokane HT, Mukherjee S, Sangle SA et al Type 2 diabetic patients without cardiovascular symptoms had significant abnormal findings on ECG and 2D Echo. Control of postprandial blood sugar level was of primary importance to prevent cardiovascular abnormalities. Type 2 diabetics without cardiovascular symptoms must be screened for cardiovascular abnormalities so that early interventions can be done to prevent further progression to symptomatic cardiovascular abnormalities. There is a significant number of people having normal ECG but abnormal 2D Echo and vice versa, so not only ECG but also 2D Echo should be done to predict cardiovascular risk in type 2 diabetic patients without cardiovascular symptoms. [14]

Uddhav K, Gupta, S.et al Assess echocardiographic detection of left ventricular diastolic function and other echo findings and electrocardiographic findings in diabetes mellitus patients excluding other comorbidities. Duration of Diabetes, HbA1C, Age (Yrs), BMI, Fasting Blood sugar were significantly associated with diastolic dysfunction. Correlation between 2D Echo finding (IHD), the ECG finding(T inversion) and Duration of Diabetes were statistically significant.[15]

Chaudhary AK, Aneja GK, Shukla S, Razi SM et al Study the incidence of left ventricular diastolic dysfunction (LVDD) and its correlation with HbA1C in normotensive, newly diagnosed type 2 diabetic patients. Out of 100 patients 65 were males and 35 females. Mean age of the population was 50.08 ± 6.32 years. Overall incidence of LVDD was 41%. Grade 1 LVDD was most common. Mean HbA1C level of LVDD group was found higher as compared to those without LVDD. LVDD is very common at the time of diagnosis of type 2 DM even in normotensive patients independent of confounding effect of hypertension, ischemia and BMI. HbA1C and age, were found to be strong indicators of LVDD in newly diagnosed cases of Type 2 DM.[16]

NEED OF STUDY:

The biggest challenge for primary physicians is to treat cardiovascular problems in diabetes mellitus which remain undiagnosed and untreated until advanced disease causes disability or death.

AIMS AND OBJECTIVES:

PRIMARY

· To study 2D echo evaluation in Type 2 DM patients (without cardiovascular symptoms and without hypertension) with special reference to diastolic function.

SECONDARY

To Study the Grades of Diastolic Dysfunction and its correlation with severity of Type 2 Diabetes Mellitus.

MATERIAL AND METHODS

Study Design: Cross sectional study.

Study site: This study will be conducted in tertiary care hospital.

Study Period: two year

Study duration:2022-2024

Study site: Department of Medicine at a tertiary care teaching hospital

Sample population: All the patients coming to hospital and for the study of 2D echo evaluation in type 2 DM patients (without cardiovascular symptoms and without hypertension) with reference to diastolic function

iii. Sample size calculation:

According to the article:

Prevalence, Awareness, Treatment and Control of Diabetes in India From the Countrywide National NCD Monitoring Survey. [17]

The Prevalence is 9.3%

The sample size was calculated using the formula:

$n = Z^2 P (1-P)/d^2$

where Z is the critical value of the Normal distribution (for a confidence level of 95%, the critical value is 1.96).

P = prevalence of 9.3%

d is the margin of error, which is considered 5% for the study

Based on the above parameters, the sample size calculated is:

Minimum sample size for the study per group is **130** patients and above

Statistical analysis

- After data collection, data entry will be done in a Microsoft Excel short
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed
- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation
- With the help normality assumption, we most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant

Inclusion criteria:

1. Patient >18 years of age.
2. Both Male and females
3. All Patients Diagnosed with Type 2 Diabetes Mellitus.
4. All Patients Diagnosed with Type 2 Diabetes Mellitus without Cardiovascular Symptoms
5. All Patients Diagnosed with Type 2 Diabetes Mellitus without Hypertension
6. Patient who will be willing to give informed consent.

Exclusion criteria:

1. All Patients diagnosed with Type 1 Diabetes Mellitus.
2. All Patients Diagnosed with Type 2 Diabetes Mellitus with Cardiovascular Symptoms like Chest Pain, Dyspnoea, Palpitations and Black-outs.
3. All Patients Diagnosed with Type 2 Diabetes Mellitus with Hypertension.
4. Type 2 Diabetes Mellitus Patients with Previous History of Cardiovascular Diseases.

DATA COLLECTION:

- Adult patients of type 2 DM coming to tertiary care hospital, either for out-patient advice or indoor treatment and who were willing to participate in the study, will be included.
- Sociodemographic information was obtained through a self-reporting questionnaire.
- Clinical information will be collected from the patients' medical records such as diagnosis of diabetes *Mellitus*, dry weight and height (for calculation of Body Mass Index [BMI]), and results of biochemical exams performed up to 30 days before the investigation.

- These patients will be without cardiovascular symptoms like palpitations, chest pain, blackout, or breathlessness.
- Their ECG and 2D echo findings will be noted and correlated with their blood sugar level fasting and post prandial and HbA1C.

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16. Chaudhary AK, Aneja GK, Shukla S, Razi SM. Study on Diastolic Function in Newly Diagnosed Type 2 Diabetes Mellitus and its Correlation with Glycosylated Haemoglobin (HbA1C). J Clin Diagn Res. 2015 Aug;9(8):OC20-2.
17. Prashant Mathur*†, Sravya Leburu† and Vaitheeswaran Kulothungan. Prevalence,Awareness,Treatement and Control of Diabetes in India From the Countrywide National NCD Mmonitoring Survey

16) TIMELINE CHART:

Stages of Research Project	**June 2022**	**July 2022**	**Aug 2022-Oct 2022**	**Nov 2022 – March 2024**	**April 2024-June 2024**	**July 2024 – Sept 2024**
1). Literature search for research topic						
2). Selection of thesis topic						
3). Institutional ethical committee						
4). Online submission of title and synopsis of dissertation to MUHS						

5). Data collection and tabulation of records						
6). Compilation and analysis of data						
7). Write-up and final submission						

17) ANNEXURES:

PROFORMA

Basic information

Patients Age : _____ Date: _____ Time: _____

Sex/Age : _____

Occupation : _____ Interviewer Phone Number: _____

Symptoms and Duration : _____

Past History: _____

Family History: _____

_____

General Examination: _____

P-
BP-
SpO2-
Pallor- Y/N
Clubbing- Y/N
Icterus- Y/N
Lymphadenopathy-Y/N
Oedema-Y/N

CNS

CVS

RS

Systemic Examination: PA

Investigations

CBC : Hb
TLC
N
L
E
B
PLC

RFT: CREAT- BUN-

LFT

Serum Electrolytes
BSL (Fasting and Post-Prandial)
Hb1AC
ECG
2D ECHO

सहमति पत्र

"डायस्टोलिक फ़ंक्शन के विशेष संदर्भ में कार्डियोवैस्कुलर लक्षणों के बिना और उच्च रक्तचाप के बिना टाइप 2 मधुमेह मेलिटस रोगियों में 2 डी इको मूल्यांकन का अध्ययन करने के लिए " नामक शोध अध्ययन के मामलों में से एक के रूप में भाग लेने के लिए तैयार हूं।

2. मुझे इस शोध अध्ययन के बारे में ऑडियो-विजुअल माध्यमों से विस्तार से जानकारी दी गई है।

3. मुझे विभिन्न जटिलताओं के बारे में भी बताया गया है; चिकित्सा या तकनीकी, अस्थायी या स्थायी, तत्काल या दीर्घकालिक आदि जो इस अध्ययन के दौरान उत्पन्न हो सकते हैं और उन्हें अध्ययन के संबंध में प्रश्न पूछने की अनुमति दी गई है।

4. यह मुझे मेरी समझ की भाषा में समझाया गया है।

5. सभी जानकारी को समझने के बाद, मैं बिना किसी बल या जबरदस्ती के इस सहमति पत्र पर हस्ताक्षर कर रहा हूं।

रोगी/रिश्तेदार/साथी के हस्ताक्षर

दिनांक:

गवाह के हस्ताक्षर:-

दिनांक:

संमती पत्र

"डायस्टोलिक फंक्शनच्या विशेष संदर्भासह हृदय व रक्तवाहिन्यासंबंधी लक्षणे नसलेल्या आणि उच्च रक्तदाब नसलेल्या टाइप 2 मधुमेह मेल्तिसमधील 2d इको मूल्यांकनाचा अभ्यास करणे" या शीर्षकाच्या संशोधन अभ्यासासाठी मी एक प्रकरण म्हणून भाग घेण्यास इच्छुक आहे.
2. मला या संशोधन अभ्यासाबाबत दृकश्राव्य माध्यमातून सविस्तर माहिती देण्यात आली आहे.

3. मला विविध गुंतागुंतांबद्दल देखील माहिती देण्यात आली आहे; वैद्यकीय किंवा तांत्रिक, तात्पुरते किंवा कायम, तात्काळ किंवा दीर्घकालीन इत्यादी जे या अभ्यासादरम्यान उद्भवू शकतात आणि त्यांना अभ्यासासंबंधी प्रश्न विचारण्याची परवानगी दिली आहे.

4. हे मला माझ्या समजुतीच्या भाषेत समजावून सांगितले आहे.

5. सर्व माहिती समजून घेतल्यानंतर, मी या संमतीपत्रावर कोणतीही सक्ती किंवा जबरदस्ती न करता स्वाक्षरी करत आहे.

रुग्ण/नातेवाईक/सहकारी यांची स्वाक्षरी

तारीख:

साक्षीदाराची स्वाक्षरी:-

तारीख:

Informed Consent Form

Name: Age:

Sex: Address:

ODD/IPD No. :

Doctor's Name:

I, the undersigned Mr./Mrs._____

Through this letter consent to voluntarily participate as a participant in the following study

TO STUDY 2D ECHO EVALUATION IN TYPE 2 DIABETES MELLITUS PATIENTS (WITHOUT CARDIOVASCULAR SYMPTOMS AND WITHOUT HYPERTENSION) WITH SPECIAL REFERENCE TO DIASTOLIC FUNCTION

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

- I agree that my participation in this study is voluntary.
- I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.
- I understand that my identity will not be revealed.
- I understand that the data collected during the study might be used for further research work and publication purposes.
- I have fully explained about the disease and its complications.
- I have explained about the investigations if needed during the entire process.

Patient's Signature/ Thumbprint
Date:

1] Witness Signature / Thumbprint
Relation:
Date:

2] Witness Signature/ Thumbprint
Relation:
Date:

Doctor's Signature:

PG Guide signature

Date: Date:

HOD Signature

Date:

JMF'S ACPM MEDICAL COLLEGE DHULE

Performa for submission of synopsis to B Performa for submission of synopsis to B

NAME OF THE POSTGRADUATE STUDENT	DR. SHUBHAM BHARAT HEKARE
NAME OF THE GUIDE AND DESIGNATION	DR.DHANANJAY NEWADKAR,MBBS,MD PROFESSOR AND HEAD OF DEPARTMENT - DEPARTMENT OF PATHOLOGY
COURSE AND SUBJECT OF SPECIALISATIONS	MD PATHOLOGY
DATE OF ADMISSION TO THE COURSE	12/11/2022
TITLE OF STUDY/DISSERTATION	HISTOPATHOLOGIC STUDY OF THE SPECTRUM OF UPPER GASTROINTESTINAL TRACT LESIONS BY ENDOSCOPIC BIOPSIES

JMF's ACPM Medical College Dhule

Proforma for Submission of Synopsis to BORS

Histopathologic Study of the Spectrum of Upper Gastrointestinal Tract Lesions by Endoscopic Biopsies

Name of the postgraduate student :

Dr.Shubham Bharat Hekare

Name of the guide and designation:

Dr.Dhananjay Newadkar

MD Pathology

Head of department

Department of pathology

Course and subject of specialization:

MD Pathology

Date of admission to the course:

12/11/2022

Title of the study / dissertation:

Histopathologic Study of the Spectrum of Upper Gastrointestinal Tract Lesions by Endoscopic Biopsies

Introduction:

The upper gastrointestinal flexible fibre optic endoscope was first used in 1968 and is proved to be major breakthrough in the diagnosis of gastrointestinal tract lesion[1].There is a marked increase in diagnostic procedures involving visualization and biopsy of the upper and lower GIT with introduction of flexible endoscopy.

Upper gastrointestinal tract disorders are one of the most commonly encountered problems in clinical practice with a high degree of morbidity and mortality[2]. A wide variety of infections, inflammatory disorders, vascular disorders, mechanical conditions, toxic and physical reactions, including radiation injury and neoplasm may occur in the esophagus and stomach[3].Endoscopy provides a unique opportunity to visualize the mucosal surface of GI tract. Endoscopy is incomplete without biopsy and histopathology is the gold standard for the diagnosis of endoscopically detected biopsy. Upper GI endoscopy in combination with biopsy plays an important role in the diagnosis of GI lesion[4].

Diagnostic endoscopy is a safe, simple and well tolerated procedure[5].Upper gastrointestinal endoscopy is performed to investigate symptoms such as weight loss, haematemesis, melena, dyspepsia, heartburn, dysphagia, abdominal pain, or in the workup of patient with anemia.It is done in asymptomatic patients as screening for neoplasia.[6]

Advanced age and alaraming symptoms such as dysphagia, gastrointestinal bleeding, vomiting,anemia,loss of weight and appetite suggest malignancy[7].Upper GI endoscopy along with biopsy plays an critical role in the early diagnosis of GI neoplasims and gives an opportunity for a broad range of treatment options with a potential for possible cure. The other indications for upper GI tract endoscopic biopsy includes- evaluation of dyspepsia, odynophagia, GERD, Barrett oesophagus, dysplasia,peptic ulcer disease and its complications, and oesophageal carcinoma.[8]

Gastric mucosal lesions especially atrophy, intestinal metaplasia and dysplasia can be detected at an early stage by endoscopic screening so as to prevent progression of lesions to invasive cancer.Biopsy and histological examination provide an adjunct to endoscopic assessment of the gastrointestinal tract and in diseases such as cancer,celiac disease and chronic inflammatory bowel disease.

Endoscopy is incomplete without biopsy and histopathology is the gold standard for the diagnosis of endoscopically detected biopsy.Upper GI endoscopy in combination of biopsy plays an important role in the diagnosis and treatment of GI lesion.

Review of literature-

The practice of gastroenterology has been challenging because of non-specific and overlapping symptomatology exhibited by lesions of upper gastrointestinal tract ranging from benign and malignant lesions difficult.Moreover malignant lesions have a long natural history and may present at a fairly advanced stage. They generally manifest late in the course before they can become sufficiently large to cause specific symptoms. Early diagnosis in such cases is therefore a challenge, the importance of which cannot be overemphasized.

Before the advent of endoscopy the practice of gastroenterology mainly involved empirical and symptomatic treatment of the vague, nonspecific and often overlapping symptoms. Precious time was lost before the persistence of a symptom or development of more specific symptoms would warrant further investigations. The chances of successful treatment is better if the lesions are diagnosed in the earliest stages and this delay would seriously jeopardize the outcome in a malignancy.

Endoscopic examination has enabled direct visualization of the lesions and enabled clinicians to provide targeted therapies rather than the empirical and symptomatic treatment of the past. The development of rigid to flexible to fiberoptic endoscopes has in true sense given them the eyes to see beyond the haze of the vague clinical presentations. The biopsy of the lesion is taken and then studied histopathologically for the final diagnosis. The affords accurate and timely diagnosis resulting in more favorable outcomes.

AIMS AND OBJECTIVES OF THE STUDY:

PRIMARY OBJECTIVE:-

1.To study the histomorphological detection of pattern and frequencies of lesions reported in upper GI tract on endoscopic findings.

2.To correlate clinical and endoscopic findings with histological findings.

OTHER OBJECTIVES: -

1.To determine the non neoplastic and neoplastic lesions of above cases.

RESEARCH QUESTIONS

PRIMARY RESEARCH QUESTION: –

1. What is the spectrum of lesions diagnosed on upper gastrointestinal endoscopic biopsies ?

2. Is there histopathological correlation of lesions with endoscopic findings?

SECONDARY RESEARCH QUESTION :

What are the patterns of lesions on endoscopic biopsy specimens according to age, gender, site and histopathology?

HYPOTHESIS:

Histopathological and endoscopic biopsy specimens correlation to get accurate diagnosis and correlate them with endoscopic findings.

MATERIAL AND METHODS:

STUDY SOURCE :

The present ambiceptive study will be carried out in Department of Pathology in ACPM Medical College Dhule .

For retrospective cases, slides of every case as per the records maintained in the histopathology department will be analysed and re-examined.

For prospective study cases, the upper GI biopsy specimens will be routinely processed and stained.

STUDY DURATION;

The present ambiceptive study will be carried out from January 2023 to November 2025.

STUDY POPULATION:

All of the upper gastrointestinal tract endoscopic biopsy lesions received in the Department of Pathology in tertiary care centre that were recorded in the pathology register within the study period will constitute the material for the study.

SAMPLE SIZE: AT 5% margin of error and 95% confidence level the recommended sample size is 73 and above.

SAMPLE FORMULA: In terms of the numbers you selected above, the sample size n and margin of error E are given by

$$x = Z(^c/100)^2 r(100-r)$$

$$n = Nx/_{((N-1)E2 + x)}$$

$$E = sqrt[^{(N-n)x}/_{n(N-1)}]$$

where N is the population size,r is the fraction of responses that you are interested

STUDY DESIGN: Cross sectional study.

NAME AND PLACE WHERE THE STUDY WILL BE CONDUCTED :

The present study will be carried out in department of pathology in ACPM Medical College Dhule.

DATA ANALYSIS AND DATA REPRESENTION:

The data will be obtained from histopathological diagnosis by processing endoscopic biopsies through various stages of tissue processing. 3 -5 µ sections will be stained with haematoxylin and eosin stains.The statistical analysis will be carried out and specific statistical test will be applied.

METHOD:

The study material will include the endoscopic biopsies those will be fixed in 10% buffered formalin and routinely processed, paraffin embedded, sectioned and stained with hematoxylin and eosin.The blocks will be cut and restained also for special stains whenever required for re- establishing the diagnosis. The study will be approved and permitted by ethics committee of the institution. After detailed study of the sections under the light microscope the final diagnosis will be given. Then, data will be analysed and results will be obtained.

INCLUSION CRITERIA:

All gastrointestinal endoscopic biopsies collected within the study time frame will be used for this study.

EXCLUSION CRITERIA:

1. All biopsies with incomplete biodata, clinical history and undocumented endoscopic findings will be excluded from the study.
2. All biopsies with missing blocks will be excluded
3. Biopsies with insufficient tissue will also be excluded.

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PROFORMA

Patients Name:

Age: Date:

Sex:

Reg. No:

Referred by Dr:

Dept/Unit:

Presenting Complains:

Clinical Diagnosis:

Past history / Relevant family history:

Lab Investigations:

Radiological findings:

Specimen type:

Microscopic Findings:

Additional findings:

DEPARTMENT OF PATHOLOGY

HISTOPATHOLOGY REQUISITION FORM

Patients name:- **Age/sex:-** **Date:**

Referred by Dr: **Reg.No:**

Clinical history: **Dept/ Unit:**

Clinical diagnosis:

Past history/Relevant family history/LMP/Menstrual history:

Treatment- Radiotherapy/ chemotherapy/ any other:

Signature of Medical officer.

(All operated specimen are property of Dept of Pathology. Send them to the department.)

Gross done by:

Gross written by: Sample received on:

Path accession no.: Gross done on:

Gross: No. of Blocks:

Microscopic Findings:

Impression/ Diagnosis:

Date:

Pathologist

संमती पत्र

मी .....

..... लिंग.....फोन नंबर ..... वय.....

..... राहणार .....

मला माझ्या डॉक्टरांनी हिस्टोलॉजी या चाचणी बद्दल सगळी माहीती सांगितली आहे. त्यानुसार मला सर्व समजले असुन त्यास मी संमती देत आहे व त्यातील जी माहीती डॉक्टरांच्या तपासणी मध्ये समोर येईल ती माहीती डॉक्टर हे त्यांच्या अध्ययनाकरिता वापरु शकतील यास माझी काही एक हरकत नाही. मी हॉस्पीटलला किंवा हॉस्पीटलच्या स्टॉपला व डॉक्टरांना कुठल्याही गोष्टीसाठी जबाबदार धरणार नाही.

नातेवाईकांची सही

पेशंटची सही

TIMELINE CHART

Stages of thesis project	February 2023	March-April 2023	May-June 2023	July 2023	July 2023 - February 2025	April-May 2025
1) Selection of thesis topic	■					
2) Institutional ethics committee approval		■				
3) Review of literature			■			
4) Online submission of synopsis to MUHS				■		
5) Data collection and tabulation of records					■	
6) Compilation and analysis of data					■	
7) Write-up and final thesis submission						■

Raosoft®

Sample size calculator

What margin of error can you accept? 5% is a common choice	5	%	The margin of error is the amount of error that you can tolerate. If 90% of respondents answer yes, while 10% answer no, you may be able to tolerate a larger amount of error than if the respondents are split 50-50 or 45-55. Lower margin of error requires a larger sample size.
What confidence level do you need? Typical choices are 90%, 95%, or 99%	95	%	The confidence level is the amount of uncertainty you can tolerate. Suppose that you have 20 yes-no questions in your survey. With a confidence level of 95%, you would expect that for one of the questions (1 in 20), the percentage of people who answer yes would be more than the margin of error away from the true answer. The true answer is the percentage you would get if you exhaustively interviewed everyone. Higher confidence level requires a larger sample size.
What is the population size? If you don't know, use 20000	20000		How many people are there to choose your random sample from? The sample size doesn't change much for populations larger than 20,000.
What is the response distribution? Leave this as 50%	5	%	For each question, what do you expect the results will be? If the sample is skewed highly one way or the other,the population probably is, too. If you don't know, use 50%, which gives the largest sample size. See below under **More information** if this is confusing.
Your recommended sample size is	73		This is the minimum recommended size of your survey. If you create a sample of this many people and get responses from everyone, you're more likely to get a correct answer than you would from a large sample where only a small percentage of the sample responds to your survey.

Alternate scenarios

With a sample size of	100	200	300	With a confidence level of	90	95	99
Your margin of error would be	4.26%	3.01%	2.45%	Your sample size would need to be	52	73	126

More information

If 50% of all the people in a population of 20000 people drink coffee in the morning, and if you were repeat the survey of 377 people ("Did you drink coffee this morning?") many times, then 95% of the time, your survey would find that between 45% and 55% of the people in your sample answered "Yes".

The remaining 5% of the time, or for 1 in 20 survey questions, you would expect the survey response to more than the margin of error away from the true answer.

When you survey a sample of the population, you don't know that you've found the correct answer, but you do know that there's a 95% chance that you're within the margin of error of the correct answer.

Try changing your sample size and watch what happens to the *alternate scenarios*. That tells you what happens if you don't use the recommended sample size, and how M.O.E and confidence level (that 95%) are related.

To learn more if you're a beginner, read **Basic Statistics: A Modern Approach** and **The Cartoon Guide to Statistics**. Otherwise, look at the **more advanced books**.

In terms of the numbers you selected above, the sample size n and margin of error E are given by

$$x = Z(^{c}/_{100})^2 r(100-r)$$

$$n = {}^{N\,x}/_{((N-1)E^2 + x)}$$

$$E = \mathrm{Sqrt}[{}^{(N-n)x}/_{n(N-1)}]$$

where N is the population size, r is the fraction of responses that you are interested in, and $Z(c/100)$ is the critical value for the confidence level c.

If you'd like to see how we perform the calculation, view the page source. This calculation is based on the Normal distribution, and assumes you have more than about 30 samples.

About **Response distribution**: If you ask a random sample of 10 people if they like donuts, and 9 of them say, "Yes", then the prediction that you make about the general population is different than it would be if 5 had said, "Yes", and 5 had said, "No". Setting the response distribution

JMF'S ACPM MEDICAL COLLEGE DHULE

NAME OF THE POSTGRADUATE STUDENT	**DR. PRIYANKA LALITKUMAR AGRAWAL**
NAME OF THE GUIDE AND DESIGNATION	**DR.NITIN KULKARNI (MBBS,DGO,DNB)** **PROFESSOR , DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**
NAME(S) OF THE CO-GUIDE(S) IF ANY AND DESIGNATION	
COURSE AND SUBJECT OF SPECIALISATIONS	**MS OBSTETRICS AND GYNAECOLOGY**
DATE OF ADMISSION TO THE COURSE	**27th April 2022**
TITLE OF STUDY/DISSERTATION	**EFFECTIVENESS OF TRANSCUTANEOUS ELECTRIC NERVE STIMULATION ON LABOUR PAIN AMONG PARTURIENT IN LABOUR**

Performa for submission of synopsis to BORS

TITLE OF DISSERTATION

EFFECTIVENESS OF TRANSCUTANEOUS ELECTRIC NERVE STIMULATION ON LABOUR PAIN AMONG PARTURIENT IN LABOUR.

DR. PRIYANKA LALITKUMAR AGRAWAL

UNDER GUIDANCE OF

DR. NITIN KULKARNI (MBBS,DGO,DNB)

PROFESSOR, DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

TITLE:

EFFECTIVENESS OF TRANSCUTANEOUS ELECTRIC NERVE STIMULATION ON LABOUR PAIN AMONG PARTURIENT IN LABOUR.

INTRODUCTION:

"*Mother's are magician , they turn pain into hope , hardship into lessons and tears into laughter"*

"-*Kelly*"

The pain experienced in labour is the most intense pain that many women will experience during their lives and it is affected by the processing of multiple physiological and psychological factors. [1,2,3] Labour pain is associated with adverse physiological consequences for the parturient, the progress of labour and wellbeing of foretaste potential effects of labour pain may include: increased oxygen consumption and hyperventilation resulting in hypocarbia and respiratory alkalosis ,as well as stimulation of ANS and catecholamines production; which causes increased peripheral vascular resistance, cardiac output and blood pressure, decreased placental perfusion and uncoordinated uterine aactivity.[4,5]

During labour , pain should always be relieved in ordered to reduce its deleterious eeffects.[4,5] Neuraxial analgesia during labour is the most effective method for pain relief but it is associated with certain side effects , such as maternal hypotension , decreased uteroplacental perfusion , fetal bradycardia , fever , pruritis , an increased oxytocin requirement , a prolonged second stage of labour, a higher rates of operative delivery and high costs. [5-10]

In contrast , many nonpharmacological methods of pain relief appears to be safe , non-invasive , easily applicable and inexpensive. They have few contraindications and can postpone the use of pharmacological analgesics and their associated adverse effects . Further more many nonphramacological methods of managing pain increase the satisfaction of women with their child birth experience.[2,11,12]

Pain relief during labour is an important concern in midwifery , nowadays natural birth and use of nonphramacological pain relief methods are being advocated for women in labour. A number of nonphramacological pain relief modalities are now available , including the birth ball , TENS , armotherapy , hypnosis , waterbath , cold and hot compresses. Among these TENS is used not only for women in labour ,but also for wide variety of patients with chronic pain.

TENS is widely used for chronic or postoperative pain control , either replacing or complementing analgesic drugs and is based on the gate theory of pain proposed by Melzack and Wall in 1965. According to this theory , the modulation of pain perception induced by TENS is attributed to the recruitment of A beta afferent fibers in posterior horn of the spinal cord , which would prevent / hamper the activation of the pain conducting small A delta fibers. It further decreases anxiety , increases sense of control and by providing distraction ,TENS increases a sense of well-being and thereby reduces pain in labour.[13]

TENS is neurophysiological means seems to help in relieving labour pain . Most of the pregnant women are not aware of the coping strategies for labour pain . As a result they tend to be restless and stress themselves by shouting or screaming due to pain . By using TENS women in labour can save energy without stressing themselves and make use of saved energy for pushing during second stage of labour.[14]

TENS fulfill the criteria of an efficacious , simple to administer method of pain relief with no side effect on mother and the baby. Through electrodes applied to lower back the parturient can control both the frequency and intensity of low voltage electric impulses emitted from TENS device. This study is conducted with an objective to analyse the effect of TENS on relieving labour pain among the potential mother’s who are in labour pain during first stage of labour.

RESEARCH QUESTION:

PRIMARY RESEARCH QUESTION: –

1.Does TENS acts as a efficient labour analgesic?

2. Does TENS delay the request for neuraxial analgesia during labour?

SECONDARY RESEARCH QUESTION : NIL

HYPOTHESIS:

PRIMARY HYPOTHESIS- TENS will be boon for obstetricians to give safe and effective analgesia during labour.

OTHER HYPOTHESIS - NIL

REVIEW OF LITERATURE:

Ramamoorthy Veyilmuthu, et.al., (2017), conducted a retrospective study assess the effect of transcutaneous electrical nerve stimulation on labour pain relief among primigravida and multigravida mothers. Department of obstetrics and Gynecology, PGS Hospital, Coimbatore, Tamil Nadu, India. Retrospective study data collected from 1041 women who used tens to cope up pain throughout the labour. About 88% of women had vaginal delivery and had very good effect in coping up the labour pain and could be used during first stage and second stage of labour. [14]

Ellen D Hodnett, et.al., (2014), conducted a meta analysis study to determine the continuous support for women during childbirth. Lawerence S Bloomberg faculty of nursing university of Toronto, Toronto, Canada. 22 trials involving 15,288 women met inclusion criteria and provided usable outcome data. result are random effect analyses, unless otherwise noted and the continuous support during labour has clinically meaningful benefits for women and infants and no known harm .All women have support throughout labour and birth. [15]

M Belen Conesa Ferrer, et.al., (2013), conducted a correlation descriptive study to assess the effectiveness comparative study analysis women's childbirth satisfaction and obstetrics out comes across two different models of maternity care. There are two university hospital in south eastern pain and convenience sample 204 of the biomedical model 202 of the humanized model in the humanized model of care (p=0.005) in the analysis of the result per items statistically difference were found in the 8 of the 9 subscale. The humanized model of maternity care offer better obstetrical outcomes and women's satisfaction scores during the labour, birth and immediate postnatal period than does the biomedical model.

Deepak , Avinash Kaur Rana, et.al., (2013), conducted a quasi experimental study to assess the effect of acupressure on intensity of labour pains and duration of first stage of labour among

primigravida mothers. National Institute of Acupressure Research, Training and Treatment, Chandigarh. with a total 60 subject were enrolled and 30 in experimental group and 30 control group and pain score were assessed with numerical pain rating scale and the result were ($p < 0.001$) and it is 0.05 level of significant . Hence acupressure could be used in clinical practice in order to improve the quality of car in labour and delivery. [16]

Nasser sal sabili, et.al., (2011), conducted a prospective study to be evaluate the effectiveness of TENS on the pregnancy rate in women undergone assisted reproductive technique (ART) and embryo transfer at Tehran. 230 sample were selected, randomly. Clinical pregnancies were documented in 36 of 117 patient (38%) in the TENS group were as pregnancy rate in the control group was 19.8% (23 out of 116) pregnancy rate was highly significant in tens group ($p < 0.005$) MANOVA did not show any difference of demographic, spermparameters and number of egg by good embryo quality between two group ($p > 0.04$).

AIMS AND OBJECTIVES OF THE STUDY

AIM

To evaluate the effectiveness of transcutaneous electric nerve stimulation (TENS) on labour pain among parturient in labour.

OBJECTIVE:

PRIMARY OBJECTIVE:- To evaluate effectiveness of TENS in terms of the requirement of additional analgesic during labour.

OTHER OBJECTIVES: -

1. To assess the level of pain and behavioral responses among parturient in labour.
2. To assess the outcome interms of nature of delivery.

MATERIAL AND METHODS:

1.SOURCE OF DATA:

- ***TYPE OF STUDY:*** Randomised clinical trial.

- ***PLACE OF STUDY:*** DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY , JMF's ACPM MEDICAL COLLEGE AND HOSPITAL, DHULE .

- ***STUDY POPULATION:*** Low risk parturient with gestational age >37 weeks in labour, without any use of medication from hospital admission until TENS applied.

2.METHOD OF DATA COLLECTION:

- ***SAMPLING TECHNIQUE USED*** : Convenience sampling.
- **SAMPLE SIZE** : 168 and above
- ***SAMPLE FORMULA :*** The Prevalence is 55.69%

  The sample size was calculated using the formula:

  $$n = Z2\ P\ (1\text{-}P)/d2$$

  where Z is the critical value of the Normal distribution (for a confidence level of 95%, the critical value is 1.96).

  P = **prevalence of 55.69%**

  d is the margin of error, which is considered **7.5%** for the study

  Based on the above parameters, the sample size calculated is:

sample size for the study per group is **168 patients and abov*e***

- ***INCLUSION CRITERIA:***

  Women's in true labour.

- ***EXCLUSION CRITERIA:***

1. Pre term labour mothers.
2. Mother's with H/0 previous cesarean section .
3. High risk pregnancy which needs elective cesarean section in first place.
4. Mothers with Pacemaker or any other implanted electronic devices.
5. Mothers who have an allergic response to the electrodes, gel or tape.
6. Mothers with skin disorder.

   e.g. dermatitis, eczema.

CONSENT:

-Approval will be taken from the Institutional ethical committee.

-Written and informed consent shall be obtained from all patients.

3.MATERIAL/ INSTRUMENTS/ ARMAMENTARIAN TO BE USED IN THE STUDY :

- 1 x Elle TENS unit
- 1 x Pack of 4 self adhesive electrodes(40mm x 100mm)
- 3 x Leadwires (2 for use and 1 spare)
- 4 x AA batteries (2 for use and 2 spare)

4.PROCEDURE :

ELLE Obstetrics TENS equipment had been used for this study. The technique of TENS application involved placement of two pairs of flat electrodes on both side of the woman's thoracic and sacral spines (T10-L1 during the first stage of labour) and (S1-S4 during second stage of labour) as pain is felt at the dermatomal distribution T10 and L1.

During full dilation and stretching of the birth canal, pudendal nerve is stimulated at S2-S4 level. These electrodes provided continuous, low-intensity electrical impulses or stimuli from ELLE TENS (battery- operated) device. The pulse frequency used was between 16 Hz and 100 Hz with pulse duration of 150 μs. Two modes are available on the ELLE TENS, each with a burst and boost function (Table A).

Table A : ELLE TENS technical specifications.

	Pulse frequency (Hz)	Pulse width (μs)	Description
Burst 1	16	150*	1burst/second, 8 pulses /burst
Brust 2	32	150*	2burts/second, 8pulses/burst
Boost 1	80	150*	Continuous
Boost 2	100	150*	Continuous

* Default pulse width after mode changed (pulse width is NOT changed when switched between BURST and BOOST mode).

Mode 1 is primarily used for the earlier stages of labour. Mode 2 is used when the labour advanced and when the contractions became more frequent. The burst function button is used in between contractions which promotes secretion of endorphins and encephalins. The boost

function button was used during contractions. This gives an extra surge of power required to combat the pain during contractions. The labour ward therapist fixed the electrodes and the women operated the device themselves. The labour ward therapist ensured the proper use of the device and the position of the electrodes frequently.

5.DURATION OF STUDY : 18 MONTH (NOV 2022- APRIL 2024)

6.METHOD OF DATA ANALYSIS :

The pain index and degree of pain relief will be used as outcome measures. The percentage of pain relief will be assessed both by the postnatal women and by the therapist . (Table 1 and 2). Pain index will be calculated by multiplying the pain relief scores assessed both by the postnatal women and therapist (Table 3). The degree of pain relief will be graded accordingly by the therapist in-charge of the obstetrics and gynecological physiotherapy (Table 3).

Kaveri Shinde G3P1L1A1 WITH 37.2 WOG WITH PREV LSCS

P-76 BPM

BP-110/70 MMHG

FHS-142BPM

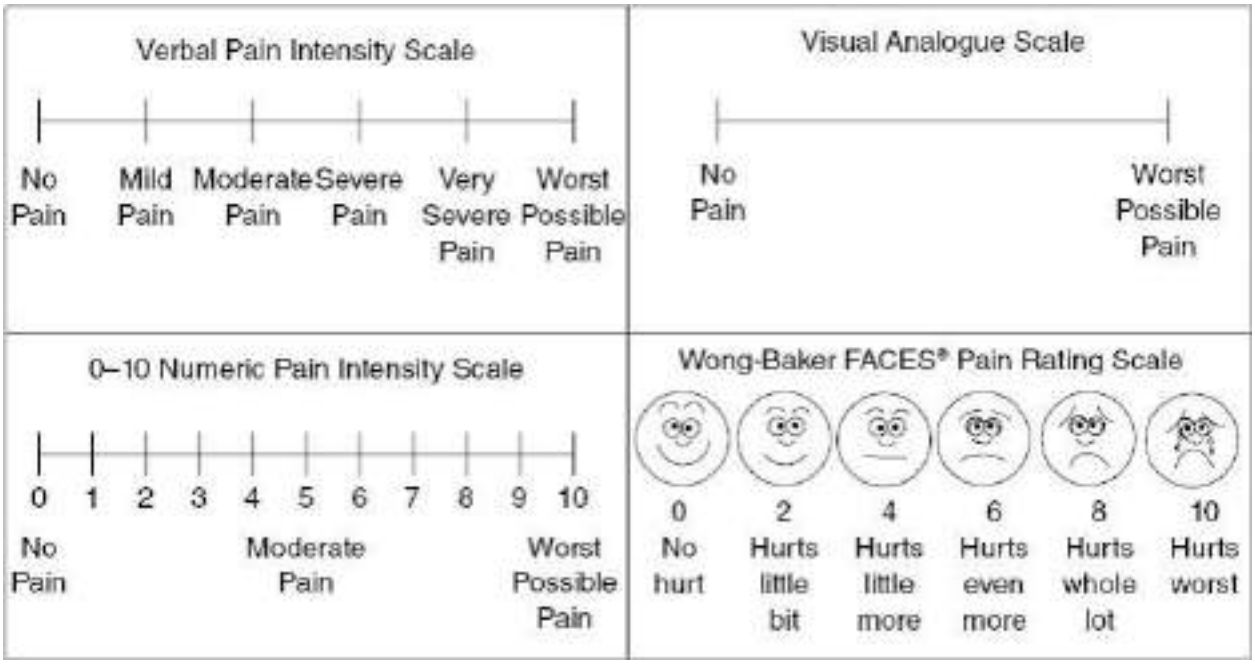

Table 1 : Scores according to percentage of relief by the participant.

Percentage of pain relief	***Score***
0-25 %	1
26-50 %	2
51-75 %	3
76-100 %	4

Table 2 : Scores according to percentage of relief by the therapist.

Description	***Percentage of pain relief***	***Score***
Moaning or shouting during contraction	0-25%	1
Wincing during contraction	26-50%	2
Restless with discomfort	51-75%	3
Comfortable and sleeping	76-100%	4

Table 3: The pain index and degree of pain relief.

Pain index.	***Degree of relief***
1-4	No relief

5-8	Fair relief
9-12	Good relief
13-16	Excellent relief

Subjective assessment of labour pain (by the postnatal women)

This variable will be standardized by visual analog scale. The distance marked will be calculated as a percentage of line length (from 0-100%). Scores will be given according to the percentage of pain relief.

Observer assessment of labour pain (by the therapist)

This grading of percentage of pain relief and scoring will be done by the labour ward therapist who attended the pregnant women during labour. Pain index will be calculated by multiplying the pain relief scores assessed both by the postnatal women and therapist. The degree of pain relief will graded accordingly by the therapist in-charge of the obstetrics and gynaecology (Table 3).

7.STATISTICAL ANALYSIS:

- After data collection, data entry will be done in a Microsoft Excel short
- Data analysis will be done with the help of statistical software SPSS (v 21.0)
- Data will be presented in tables as well as figures, wherever needed
- Descriptive statistics will be used to note down the distribution of patients based on age, gender, patient history details, clinical features and complications.
- Quantitative data will be presented with the help of Mean and Standard deviation

- With the help normality assumption, we most appropriate suitable statistical tests (parametric or non-parametric test).
- P value of less than 0.05 will be considered significant

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TIMELINE CHART:

Time line chart

Stages of Research Project	July 2022	Aug 2022	Sep 2022 - Oct 2022	Nov 2022- April 2024	May 2024	June 2024
1)Literature search for thesis topic	■					
2) Selection of thesis topic		■				
3) Institutional ethics Committee approval			■			
4) Online submission of synopsis to MUHS			■			
5) Data collection & and tabulation of records				■		
6) Compilation and analysis of data					■	
7) Write-up & final submission						■

PROFORMA

Patients Name: ***Date***:

Age: ***Sex***: ***Reg. No:***

Referred by Dr: ***Dept/Unit***:

Parity: G*P*L*A*D*

Presenting complaints:

LMP: ***EDD***: ***Gestational age:***

Menstrual History:

Obstetric History:

Past history / Relevant family history:

On examination: Afebrile

Pulse:

BP:

General examination: Pallor/Cyanosis/ Lymphadenopathy/ Clubbing/Oedema

Systemic examination:

- CVS
- CNS
- RS

Per Abdomen: Ut Ht – wks of gestation, Relaxed/ irritable ,no.of fetus, lie, presentation, FHS -bpm

Per Vaginal examination- Dilatation- cm , BOM – intact/ ruptured , station ,effacement - %

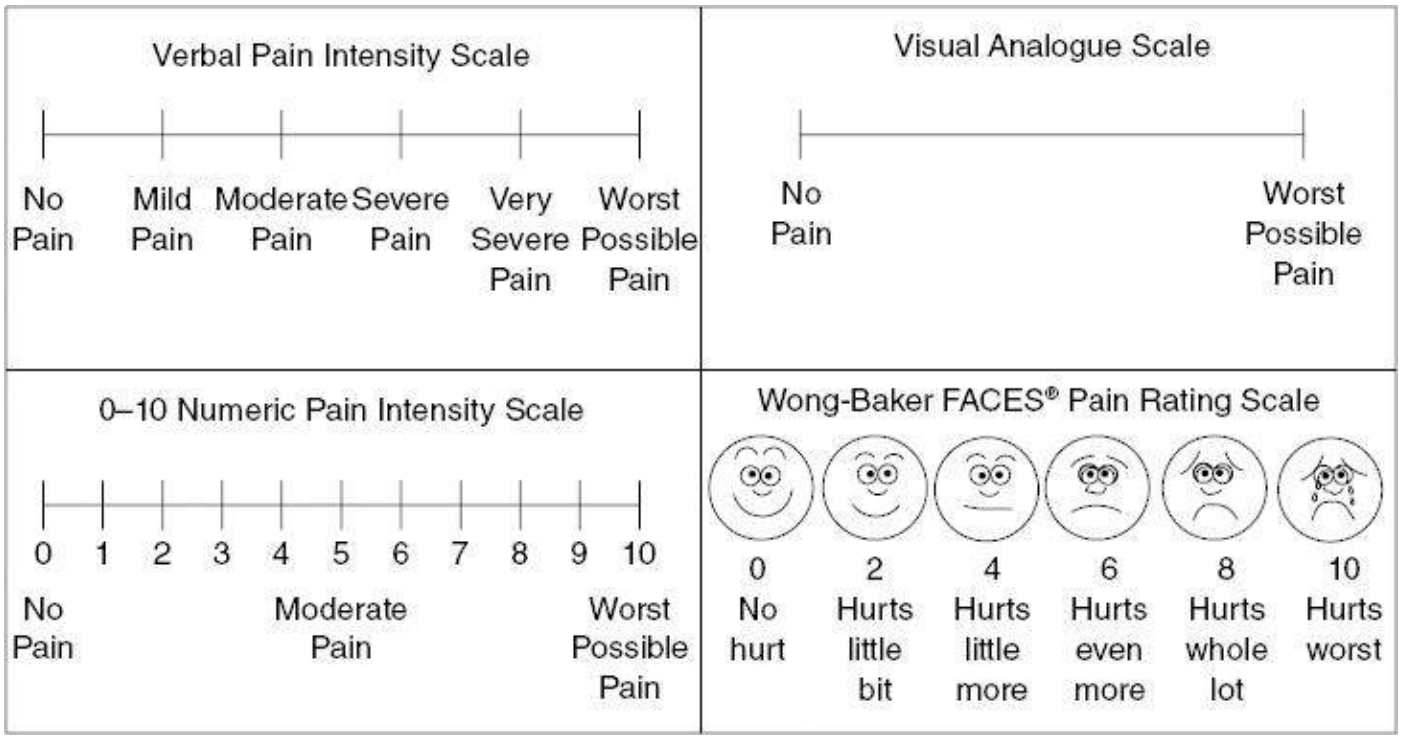
Clinical diagnosis:

Intrapartum Findings :

Duration of first stage of labour:

Duration of second stage of labour:

Type of delivery:



Pain score pretest:

Pain score posttest:

Vitals before application of TENS:

Vitals after application of TENS:

Overall satisfactory feedback:

संमती पत्र

“ प्रसूतीमधील वेदनांवर ट्रान्सक्यूटेनियस इलेक्ट्रिक नर्व्ह स्टिम्युलेशन (टेन्स) ची परिणामकारकता ”

1. या शीर्षकाच्या संशोधन अभ्यासासाठी मी एक प्रकरण म्हणून भाग घेन्यास इच्छुक आहे.

2. मला या संशोधन अभ्यासाबाबत दृकश्राव्य माध्यमातून सविस्तर माहिती देण्यात आली आहे .

3. मला विविध गुंतागुंतांबद्दल देखील माहिती देण्यात आली आहे; वैद्यकीय किंवा तांत्रिक, तात्पुरते किंवा कायम, तात्काळ किंवा दीर्घकालीन इत्यादी जे या अभ्यासादरम्यान उद्भवू शकतात आणि त्यांना अभ्यासासंबंधी प्रश्न विचारण्याची परवानगी दिली आहे.

4. हे मला माझ्या समजुतीच्या भाषेत समजावून सांगितले आहे.

5. सर्व माहिती समजून घेतल्यानंतर , मी या संमतीपत्रावर कोणतीही सक्ती किंवा जबरदस्ती न करता स्वाक्षरी करत आहे.

रुग्ण/नातेवाईक/सहकारी यांची स्वाक्षरी

तारीख:

साक्षीदाराची स्वाक्षरी:-

तारीख:

INFORMED CONSENT FORM

Name: Age:

Sex: Address:

ODD/IPD No. :

Doctor's Name:

I, the undersigned Mr./Mrs._____

Through this letter consent to voluntarily participate as a participant in the following study

EFFECTIVENESS OF TRANSCUTANEOUS ELECTRIC NERVE STIMULATION (TENS) ON LABOUR PAIN AMONG PARTURIENT IN LABOUR

The concerned researcher has explained me the nature of the study and cleared all my doubts accordingly.

I agree that my participation in this study is voluntary.

I understand that I am free to withdraw at any time, without giving any reason and without my medical care being affected.

I understand that my identity will not be revealed.

I understand that the data collected during the study might be used for further research work and publication purposes.

I have fully explained about the disease and its complications.

I have explained about the investigations if needed during the entire process.

Patient's Signature/ Thumbprint

Date:

1] Witness Signature / Thumbprint

2] Witness Signature/ Thumbprint

Relation:

Relation:

Date:

Date:

Doctor's Signature:

PG Guide signature

Date:

Date:

HOD Signature

Date

TITLE AND SYNOPSIS

Sr. No	Item	Guideline
01	Title	To compare the efficacy of Dexamethasone and Betamethasone for fetal lung maturity and fetal outcome in preterm labour cases. A prospective observational study in a tertiary health care center.
02	Introduction	As per World Health Organization (WHO), a preterm baby is defined as a baby who is born alive before 37 weeks of pregnancy are completed.[1] Prematurity constitutes a serious complication in the field of obstetrics worldwide. The global incidence of preterm birth is around 10-15%.[2] India has the highest number of preterm births as well as neonatal deaths due to prematurity. Out of an estimated 2.6 crore live births in India each year, 35 lakh babies are born preterm, and out of these, 3.03 lakh babies (10% approximately) die due to complications of preterm births. Preterm birth is a risk factor in at least 50% of all neonatal deaths and is the second most common cause of death (after pneumonia) among children under the age of five. Various untoward outcomes like respiratory distress syndrome, intra-ventricular haemorrhage, retinopathy of prematurity, necrotizing enterocolitis, low birth weight, neonatal mortality are associated with premature birth.[1] Antenatal corticosteroids are effectively used for acceleration of fetal lung maturation in preterm delivery. The two common antenatal

		corticosteroids recommended and widely used are dexamethasone and betamethasone. According to ACOG, RCOG and WHO both dexamethasone and betamethasone are effective for prevention of prematurity related neonatal morbidities and mortality.[2] Antenatal corticosteroids have shown to accelerate development of type 1 and type 2 pneumocytes, which leads to structural and biochemical changes, thus improving lung mechanics like lung volume, compliance and gaseous exchange.[3, 4] Type 2 pneumocytes helps in production of surfactant by providing surfactant proteins and enzymes required for synthesis of phospholipid.[3, 4] Antenatal corticosteroids also induce pulmonary beta-receptors, which result in release of surfactant and absorption of alveolar fluid.[5]They also stimulates synthesis of fetal lung antioxidant enzymes.[6] They play a significant role in upregulation in the gene expression for epithelial Na+ channels which are required for absorption of lung fluid post birth.[4] The physiologic effects of antenatal corticosteroid administration include accelerated cyto differentiation, greater maturity of cerebrovascular endothelial cells and autoregulation of cerebral perfusion, and increased activity of antioxidant enzymes, which lessens the risk of neurologic cell damage.[7] It is well known that administration of antenatal corticosteroids to women at high risk of preterm delivery reduces neonatal morbidity and mortality. However, previous studies provide conflicting results in

		respect to the choice of corticosteroid to be used for the same. The preference of one drug over the other depends on various factors including efficacy, availability and affordability. A thorough review of literature suggests very few studies done in India. Therefore, we plan this study to bring into light the best treatment modality applicable in an Indian scenario.
03	Research question	Which drug is better for the lung maturity in preterm labour cases, Dexamethasone or Betamethasone? What are the various fetal outcome by means of morbidity and mortality in preterm labour cases receiving Dexamethasone and Betamethasone?
04	Hypothesis	Not applicable
05	Review of literature	Preterm newborns are classified on the basis of completed gestation period as: **Extremely Preterm – Less than 28 weeks** **Very Preterm – 28 to <32 weeks** **Late and Moderate Preterm – 32 to <37 weeks** The relative proportion of these groups is 5%, 10% and 85%, respectively. The mortality rate among preterm newborns increases with decreasing gestational age.

		Timely use of Antenatal Corticosteroids in a mother reporting with preterm labor before 34 weeks of gestation has the following clinical impacts in newborn who receive good supportive care, **34% reduction in Respiratory Distress Syndrome (RDS),** **46% reduction in Intra Ventricular Hemorrhage (IVH),** **54% reduction in Necrotizing enterocolitis (NEC) and** **31% reduction in mortality.** Studies have shown that near universal coverage of this intervention can reduce 40% of mortality amongst neonates. Also, it has been reported that use of Antenatal Corticosteroids leads to other benefits too like reduction in the incidence of PDA, reduction in systemic infections, decreased need for respiratory support and therefore, reduced length of hospital stay, low rate of intensive care admissions and finally reduced cost of care.[1] Betamethasone and dexamethasone have generally been the preferred corticosteroids because of their beneficial effect on fetal organ development. These agents have relatively good placental transfer, a long half-life and duration of activity, identical biologic effects, little mineralocorticoid activity, and relatively weak immunosuppressive activity.[8] In 1994, the National Institutes of Health (NIH) recommended either two 12 mg doses of betamethasone given intramuscularly 24 hours

		apart or four 6 mg doses of dexamethasone given intramuscularly 12 hours apart between 24 and 34 weeks of gestation.[8] Dexamethasone listed in the WHO essential medicines list, is inexpensive and widely available in facilities for multiple indications. In India, the salt Betamethasone acetate + phosphate, which requires only two doses at 12 hourly interval, is not available. The available salt in India is Betamethasone phosphate which is short acting and requires more frequent administration as compared to the former. Hence, the dosage schedule of Betamethasone phosphate is similar to that of the Dexamethasone and has no added advantage over Dexamethasone. Further, Betamethasone is more costly and less stable than Dexamethasone at high temperatures. However, in individual cases where Inj. Dexamethasone is not available the service provider may use Inj. Betamethasone phosphate to give the advantage of corticosteroids to the newborn.[1] **Maji A et al [9]** performed a prospective comparative study involving 100 pregnant women of gestational age from 28 weeks to 36 weeks + 6 days with preterm labour. Patients were divided into 2 groups of 50 each. One group was given 4 doses of injection dexamethasone 6mg intramuscularly 12 hours apart while another group was given 2 doses of injection betamethasone 12mg 24 hours apart. They found that the neonates who were given dexamethasone prenatally showed lesser evidences of respiratory distress syndrome (30% vs 40%),

		intraventricular haemorrhage (2% vs 4%), necrotising colitis (2% vs 4%), low birth weight (40% vs 50%) and neonatal deaths (4% vs 8%) as compared to the neonates who received betamethasone before birth.[9] **Liggins et al** performed a randomized controlled study in 282 mothers and found that betamethasone 12 mg intramuscularly in two doses, 24 hours apart, prevented RDS in their preterm neonates.[10] Babies born before 34 weeks had a significant reduction in RDS and neonatal mortality if birth was delayed for at least 24 hours or up to 7 days after completion of the course of betamethasone, as substantiated by a number of other studies.[11-16] **Young et al** carried out a prospective trial of intravenous dexamethasone for prevention of neonatal RDS in 112 mothers compared with 188 untreated controls.[15]In neonates born at 28 to 33 weeks of gestation, the treatment group had half the perinatal mortality and one-fourth the incidence of severe RDS seen in the control group.[15] **Ballard et al** compared the outcome in 114 infants with birth weights between 750 and 1,750 g whose mothers received antenatal betamethasone therapy with that in 138 infants born to untreated mothers. The incidence of RDS after betamethasone was 37.7% compared with 50.7% without treatment.[12]

		Doran et al performed a double-blind controlled study of antenatal betamethasone treatment in 137 patients from 24 to 34 weeks of gestation. The incidence of RDS was less in the treated group (5%) than in the control group (17%), and neonatal mortality was lower in the treated group (5%) than in the control group (18%).[14] **Maher et al** retrospectively reviewed a group of very preterm infants born to 432 women who delivered at 26 to 31 weeks.[17]Of these mothers, 67 had received antenatal betamethasone and 365 had not. When betamethasone was administered at least 2 days before delivery, there was a lower incidence of RDS in both the 26–28-week group (53.9% vs 86.5%) and the 29–31-week group (25.0% vs 59.1%), compared with the untreated group.[17] **Crowley et al** analyzed data from 12 controlled trials involving over 3,000 women.[18]They demonstrated that antenatal corticosteroid administration reduced the risk of neonatal RDS by 50%, and this benefit was most obvious when the interval from corticosteroid treatment to delivery was between 24 hours and 7 days.[18] **Morales et al** carried out a prospective, blinded, randomized study of antepartum dexamethasone administration in 250 women between 28 and 33 weeks' gestation who had preterm premature rupture of membranes (PPROM).[19]The dexamethasone-treated group had a lower incidence of IVH.[19] **O'Shea et al** collected data on 201 neonates with very low

		birth weights, and found that maternal treatment with betamethasone was associated with a decreased incidence of IVH.[20] **Garite et al** performed a double-blind clinical trial of antenatal betamethasone treatment in mothers with intact membranes and threatened premature delivery between 24 and 28 weeks' gestation.[21] The treatment group of 36 mothers received two 12 mg doses of betamethasone, 24 hours apart, while 41 mothers received placebo. The incidence of grade 3 (blood acutely distending the lateral ventricles) and grade 4 IVH (blood within the ventricular system and parenchyma) was lower in the betamethasone-treated group (betamethasone vs placebo, 1/31 vs 9/36; $p = 0.01$).[21]**Linder et al** studied a cohort of 641 preterm neonates with a birth weight of less than 1,500 g, of whom 36 had grade 3 or 4 IVH.[22] **Baud et al** performed a retrospective analysis of 883 infants born between 24 and 31 weeks of gestation.[23]In this series, 361 mothers received antenatal betamethasone, 165 mothers received dexamethasone and 357 mothers did not receive any glucocorticoid. The incidence of PVL was 4.4% in neonates in the betamethasone group, 11.0% in the dexamethasone group and 8.4% in the no-treatment group. Betamethasone was thus associated with a lower incidence of PVL compared with no glucocorticoid therapy (OR, 0.5; 95% CI, 0.2–0.9) and dexamethasone (OR, 0.3; 95% CI, 0.1–0.7).[23]

		Canterino et al carried out another retrospective cohort study that included 1,161 neonates born between 24 and 34 weeks with birth weights of 500–1,750 g.[7] They found that neonates of mothers treated with antenatal betamethasone had a 56% lower risk of PVL with IVH (OR, 0.44; 95% CI, 0.25–0.77) and a 58% lower risk of isolated PVL (OR, 0.42; 95% CI, 0.20–0.88). [7]
06	Objectives	1. To compare the efficacy of Dexamethasone and Betamethasone for fetal lung maturity in preterm labour cases at tertiary health care center. 2. To compare the various fetal outcome by means of morbidity and mortality in preterm labour cases receiving Dexamethasone and Betamethasone.
07	Research methodology specified and explained for data collection	All the patients with preterm labour admitting in Obstetrics and gynecology ward during the period of October 2022 to September 2023, at tertiary health center, will enrolled in study. **STUDY SETTING** Tertiary health care center **STUDY DESIGN** This is a prospective and observational study at tertiary health care center. **STUDY POPULATION**

		All the patients with preterm labour admitting in Obstetrics and gynecology ward during the period of October 2022 to September 2023, at tertiary health center **STUDY DURATION:** 1 year **SAMPLE SIZE:** 160 cases of preterm labour **SAMPLE SIZE CALCULATION:** Samlpe size is calculated by using the formula $N= 4 X PQ/E^2$ N: Sample size P: Prevalence of eclampsia (which is 10% $=0.1)^2$ Q= 100-Prevalence = 100-0.1, = 99.90 E: Error, we are taking error as 0.5% Therefor, $N= 4 X 0.1 X 99.90/ 0.5^2$ N= 159.84 N=160 • **Inclusion Criteria:** • Pregnant females presenting with preterm labour between the gestational age of 28 weeks to 36 weeks + 6 days. • Patients willing to give informed written consent. • **Exclusion Criteria:** • Multiple pregnancies

		• History of preeclampsia • Previous history of heart disease and epilepsy • History of Gestational diabetes mellitus (GDM) • History of severe anaemia • History of corticosteroid used in last 2 months. • Those not giving written informed consent. • **ETHICAL CONSIDERATION** • This study will be conducted in compliance with the protocol, the Institutional Ethical Committee (IEC), and informed consent regulations. Before initiating the study, the investigator will have written and dated approval from the IEC for the following documents: study protocol/amendment(s), written informed consent form, Case Report Forms, and protocol summary. During the study, any amendment or modification to the study protocol will be submitted to the ethics committee (IEC). It should also be informed of any event likely to affect the safety of patients. Progress report and study completion report also must be sent to IEC. • **INFORMED CONSENT** • The investigator, will explain the benefits and risks of participation in the study to each women to the fullest extent possible about the study, in language and terms they are able to understand. Subsequently a written informed consent prior to

		the patient's entering the study (i.e., before initiation of routine tests) will be obtained from parents. Each patient's original consent form, signed and dated by the patient's parents. • **METHODOLOGY** • All the patients with preterm labour admitting in Obstetrics and gynecology ward during the period of October 2022 to September 2023, who fulfil the inclusion criteria, will enrolled as study population. • It is a prospective observational study. After the enrolment, patients will be divided in two groups, Group A and Group B. • Patients in Group A will received 4 doses of Injection Deaamethasone 6 mg 12 hourly and patients in Group B will received 2 doses of injection Betamethasone 12 mg 24 hourly. • A pre-designed case record form (CRF) was used to collect demographic details like name, age, address along with data about physical examination and clinical history. • Other important parameters like parity, booking status, gestational age at presentation at arrival to hospital will be recorded in CRF. • Treatment modality employed, mode of delivery, fetal morbidity and mortality and need to admit in NICU will be recorded.

		• Under aseptic precaution blood will collected and send for following investigation and their finding will recorded in CRF. All the investigation will performed in tertiary health centre. • **First line investigation (will be done in all cases)** • Haemoglobin • CBC, TLC and differential leukocyte count, CRP • Blood glucose • KFT • LFT • Sr. Electrolyte (Sodium, Potassium and Calcium) • Urine routine (for proteinuria) • **DATA ENTRY AND STATISTICAL ANALYSIS** • Data will recorded in pre structure case record form. From this CRF, data enter in MS Excel and appropriate software and test will apply to find the statistical significant difference. P value <0.05 will be considered as statistical significant. For the comparison of qualitative data, Chi-square or Fishers exact test will be used. For the comparison of quantitative data, student unpaired 't' test will be used. The confidence limit for significance was fixed at 95% level with p value <0.05. • **Funding and Expenses:** • This study is not funded by any agency and there is no financial disclosure to be made.

		• **Insurance, if any:** None • **Conflict of interest:** None
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09	**Timeline/ Gantt Chart :-**	Attached below
	Annexures :-	**Annexure 1**-Case Record Form **Annexure 2-**English Consent form **Annexure 3-**Marathi Consent Form **Annexure 4-**Hindi Consent Form **Annexure 5-**Gantt chart