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RESEARCH ARTICLE

ROLE OF ANTIBIOTIC IMPREGNATED CEMENT COATED INTRAMEDULLARY NAILING IN ORTHOPAEDICS

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Abstract

Introduction: Traditionally,thetreatmentstrategyofinfectednon-unionconsistedofsurgicaldebridementandthenasecondprocedureforstability.Theuseofanantibioticcementednailingforinfectednon-unionoftibiaandfemurfracturesavoidstheneedofmorethan1procedureasthenailprovidesstabilityandallowshigherconcentrationofantibioticatthelocalsitethanisachievablewithsystemicantibioticsandisassociatedwithfewersideeffect.

MaterialandMethods: Thisisaprospectivestudyof12patientswithdiaphysealfractureoftibiaorfemurwithsignsofinfectionwhoweretreatedusingantibioticcementednailing.Patientswerefollowedupmonthlyfor3months.Infectioncontrolwasevaluatedintermsofclinical,haematologicalandmicrobiologicalparameters.

Results: Atthetimeofpresentation11outof12patientshadpusdischarge,whilelocalriseoftemperaturewasthereinallpatients.Mostcommonorganismthatwasisolatedinculturewas Staphylococcusaureus.ESRandCRPwaselevatedin9patients.At3monthsfollowupvisit,9outof12patientsresolvedallsignsofinfectionwhile1hadpersistentpositiveculturereports.ESRandCRPwasraisedin3and2patientsrespectively.

Conclusion: Antibioticcementednailingdeliversahighconcentrationofantibioticsatthelocalsitewithoutcausinganysystemictoxicityalongwithprovidingstabilityatthefracturesite,therebyconvertingatwo-stageprocedureintoasinglestageprocedurewhichalsoavoidscomplicationsofexternalfixatorhavingbetterpatientcompliance.

Introduction:-

Non-unioninthepresenceofinfectionpresentswiththedualproblemsofcontrollinginfectionandprovidingstability.Variousfactorscontributetoinfectednon-

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union,includingopenfractures,infectionafterinternalfixation,[1]chronicosteomyelitiswithpathologicalfractures,andsurgical debridementofinfectedbone.Traditionally,thetreatmentstrategyconsistedofsurgicaldebridementwithlocalandsystemicantibioticdeliveryandthenasecondprocedureforstability,generallyeitherinternalorexternalfixation.Itbecomesdifficulttodealwhentheimplantusedforinternalfixationitselfbecomesapotentialmediaforinfectionbecauseofbacterialadhesionanddbiofilmformation.[5]Specialreconstructiveproceduresandsofttissueproceduresmightalsobenecessary.[1,2]

Mostoftheorthopaedictraumainfectionsarecausedbybiofilm-formingbacteria[5].Biofilmconsistsofhydratedmatrixofpolysaccharideandprotein.Onceformed,itprotectsthemicroorganismfromantimicrobials,opsonization,andphagocytosis,thuscontributingtothechronicityofinfections[6].Inordertocurebiofilm-relatedinfection,fourprinciplesformulatedbyCiernyandMadermustbeobserved:(1)completesurgicaldebridementwithdeadspacemanagement,(2)fracture/non-unionstabilization,(3)softtissuecoverage,and(4)adequateantibioticlevels[7].Localantibiotictherapyisausefultechniquethatresultsinhighlocalconcentrationsofantibioticswithminimalsystemiclevels.[3]Thismethodintheformofantibioticimpregnatedpolymethylmethacrylate(PMMA)beadsisusedinthetreatmentofosteomyelitisandopenfractures.[1,4]Althoughthistechniquepromotescontrolofinfection,anadditionalprocedureisrequiredforremovalofthebeads.Withthegoalofavoidingmorethan1procedureinthesepatients,wepresentoursingle-proceduretechniqueoftreatmentwithaKnailcoatedwithantibiotic-impregnatedbonecement,whichcombineslocalantibioticdeliverywithstableinternalfixation.

TheuseofanantibioticimpregnatedcementcoatedIMnailingforinfectednon-unionoftibiaandfemurfractureshasbeenwell-documentedintheliterature[8-15].Thecementnailprovidesstabilityacrossthefracturesite,unlikecementbeadsandosseousstabilityisimportantinthemanagementofaninfectednon-union[14,15].Secondly,antibioticcementallowshigherconcentrationatthelocalsitethanwhichisachievablebysystemicantibioticsandisassociatedwithfewersideeffects.Antibioticcementhasbeenshowntoeluteantibioticatthelocalsiteforupto36weeksthusprovidingatherapeuticeffectonrefractoryinfection[13,14].

Antibioticsusedforthispurposeshouldhavespecialpropertiessuchasbroadspectrumofactivity,heatstability,andlowallergenicity.Gentamicinhasbeenthemostwidelyusedantibioticfollowedbyvancomycinandteicoplanin[16,17].Inourstudy,weusedvancomycinasithasthedesiredproperties.Thepurposeofourstudywastoevaluatetheoutcomeofantibioticimpregnatedcementcoatedintramedullarynailinginthemanagementofinfectioncontrolandbonyunion.

Material and Methods:-

Thisisaprospectivestudyof12patients(11males,1female)agedbetween20to57yearswithdiaphysealfractureoftibiaorfemurwithsignsofinfection,whoweretreatedusingantibioticimpregnatedcementcoatedintramedullarynailingfromJanuary2021toJanuary2023.Patientswhowereallergictovancomycinwereexcludedfromthestudy.Patientswereevaluatedintermsofclinical,haematologicalandmicrobiologicalparametersviz,presenceofpusdischarge,localriseoftemperature,leucocytosis,ESR,CRPandculture/sensitivity.Afterthoroughpre-operativeevaluation,informedconsentwastakenforsurgery.Thefirststepincasespreviouslyoperatedinvolvedremovaloftheimplant,whichwasfollowedbydebridementoftheboneandsofttissuesandirrigationwithcopiouslavage.Thiswasfollowedbyinsertionoftheantibioticimpregnatedcementcoatedintramedullarynailintheadequatelyreamedintramedullarycanal.

Post-operatively,thewoundwasinspectedafter48hoursintervalandthepatientwasadministeredintravenousantibioticsaspercultureandsensitivityreportsfor2weeks.Thepatientwouldthenbedischargedonoralantibioticsforatimeperioddependingonindividualpatientcharacteristic,conditionofthewoundandtheorganisminvolved.

Patientswerefollowedbyfor3monthsandthenatthefinalfollowupandwereevaluatedintermsofinfectioncontrolwiththehelpofclinical,haematologicalandmicrobiologicalparameters.

Surgicaltechnique

Thesurgicaltechniqueinvolvesaseriesofsteps,eachofwhichiscriticalforsuccessfulresults.Thefirststepiscarefulpreoperativeevaluationofcultureandsensitivityresultsandradiographs.APandlateralviewradiographsoftheinvolvedboneareobtained,andthepreoperativemeasurementsofthelengthanddiameteroftheKnailarecalculatedbyusingtheseradiographs.Forthefemur,thedistancefromthepyriformisfossato1cmproximaltothetopoftheintercondylarnotchisusedasthelengthofthenail.F

orthetibia,thelengthofthenailisfromtheproximaltibialarticularsurfaceto1cmproximaltotheankleplafond.Thesecondstep involvesthoroughdebridementoftheinfectedboneandsofttissuesandthencopiouslavage.Allthenonviableandinfectedtiss ues,includingskin,softtissues,andbone,undergodebridementuntilbleedingviabletissueispresentattheresectionmargins(t hePaprikasigninthecaseofbone).Inadequatedebridementleavesnonviableorinfectedtissuesecludedfromthemicrocircula tion,resultinginrecurrenceofinfectiondespitelocalandsystemicantibioticdelivery.Thisinturnfacilitatesbiofilmformation ,whichprotectsthepathogensfromantibioticsandhostdefencemechanisms.1Specimensareobtainedofthebone,softtissues ,andanypurulentmaterialpresentandaresentforaerobicandanaerobiccultures.

Thethirdstepisthepreparationoftheantibioticcementcoatedintramedullary(IM)Knailundersterileconditionsintheoperati ngroom.Whileateamofsurgeonsperformdebridementoftheinfectednon-unionsite,anothersurgeonpreparesthenailonaseparatesteriletable.Commerciallyavailableknailsareused.AntibioticCem entispreparedbymixing4gramsofvancomycinpowderwith40gramsofbonecement.ThePalacoscementismixedinastandar dfashion,byhandmixinginabowl.Whenthecementisnolongerstickytothegloves,thecementisappliedtoknailwithaunifor mmantleof1mmandthegrooveisalsofilledwiththeantibioticcementleavingtheeyeoftheknailtofacilitateeasyremovalofkn ailinfuture.Thenailisreadytobeinsertedwhenthecementsetsusuallyin10to12minutes.

Thefinalstepsinthistechniqueinvolvepreparationoftheantibioticcement-coatednail.ReamingoftheIMcanalisperformedto1mmmorethanthediameteroftheantibioticcement-coatednail.Onemillimetreofcementmantlecoatingisprovidedaroundthenail;thefinaldiameteroftheantibioticcement-coatednailistherefore2mmmorethantheIMnailitself.Thesurgicalteammemberswhohavecompletedthedebridementchan getheirgownsandgloves.Thelimbisagainpreparedanddraped.Theantibioticcement-coatedIMnailismountedontheinsertionjigandisinsertedinthestandardfashion.Insertionofthisnailproceedssimilarlytotha tofanunreamedIMnail,exceptthattheguidewireusedduringreamingisremovedbeforeinsertionofthenailascementocclude sthecannulatedportionofthenail.Becausethenon-unionsiteisexposedduringthedebridementprocess,theIMnailcanbeinsertedthroughtheentirelengthoftheboneandacrosst hesiteofnon-unionbyusingacombinationofdirectvisualinspection,palpation,andfluoroscopicradiographicguidance.‘‘Cement-naildebonding’’(separationofthecementfromtheIMnail)canoccurduringinsertionofantibioticcement-coatedIMnailwhichcanbepreventedbyadequateover-reamingofthecanal.However,whenthisdoesoccur,thedebondedcementisremovedandanewantibioticcementcoatednailis preparedandused.

Exchangenailing,ifnecessary,isdonewithoutanantibioticcoating(generallytoalargernailforadditionalstability)iftheinfec tednon-unionhasbeenconvertedtoanon-unionwithoutinfection.Ifthereisnoinfectionandunionhasoccurred,theantibiotic-coatedknailcanberemoved.Ifbothinfectionandnon-unionpersist,theIMnailisexchangedforanotherantibioticcement-coatedIMnail,generally6to8weeksaftertheindexsurgery.

Results:-

Antibioticcement-coatedknailswereusedduringaperiodof2years(January2021toJanuary2023)in12casesofinfectednon-unions,chronicosteomyelitis(withbonedefectsafterdebridement)andprimarycompoundfractures.Outof12patients,11we remaleswhile1wasafemale.Themeanagewas32.4yearswithyoungestpatientbeing20yearsofageandoldestbeing57yearso fage.Outof12patients,6patientspresentedwithinfectednon-unionoffractures,4presentedwithchronicosteomyelitisand2presentedwithprimarycompoundfractures.Tibiawasinvolve din7patientsandfemurwasinvolvedin5patients.Only1ofallthepatientswithchronicosteomyelitisoffemurhadcomorbidity whichwasanoldpartiallyrecovereddiffuseaxonalinjurywithparaphasia.

Table1:- Gender.

	Number	%
Male	11	91.66
Female	1	8.33
Total	12	100

Table2:Age

Agecharacteristics	Age(inyears)
Minimum	20

Maximum	57
Mean±SD	32.41±10.24

Table3:- Diagnosis.

Diagnosis	Number	%
Infectednon-union	6	50
Chronicosteomyelitis	4	33.33
Compoundfracture	2	16.66
Total	12	100

Table4:- LongBoneInvolved.

Longboneinvolved	Number	%
Femur	5	41.66
Tibia	7	58.33
Total	12	100

11outof12patientshadpusdischargeatthetimeofpresentationwhile1hadcompoundfractureofshaftoftibia.Localriseoftemperaturewasthereinallpatientsatthetimeofpresentation.PreoperativeorganismwasMRSAin2patients,staphaureusin3,enterococcusin1,klebsiellapneumoniain2andnoorganismswereisolatedin4cases.Leucocytosiswasseenin3patientswhileESRandCRPwaselevatedin9patients.

Table5:- OrganismIsolatedinPusCulture.

Organism	Number	%
MRSA	2	16.66
Staphylococcusaureus	3	25
Enterococcus	1	8.33
Klebsiellapneumonia	2	16.66
Nogrowth	4	33.33
Total	12	100

During1monthfollowup,4patientsstillhadpusdischarge,5hadpersistentlocalriseoftemperaturealongwithpositivepusculturereportsamongstwhich1withcompoundsegmentalfractureofshaftoftibiaandfibularightwithboneloss,whoinitiallydidnothavegrowthinpusculturesdevelopedgrowthofpseudomonasaeruginosa.Noneofthepatientshadleucocytosis.ESRwasraisedin8patientswiththemeanbeing24±13.29.CRPwasraisedin4patientswithmeanbeing9.31±16.04.

During2monthsfollowup,2patientshadpersistentpusdischarge,whohadgrosscontaminationofthecompoundwoundandanotheronewithchronicosteomyelitisoffemur.These2patientsalsohadpersistentlocalriseoftemperature.Onepatientdevelopedlocalwarmthandabscessoverdistalaspectoflegandincisionanddrainagewasdoneandculturesshowedgrowthofklebsiellapneumonia.Patientwithpathologicalfractureoffemurduetochronicosteomyelitisalsohadpersistentpositivepuscultures showinggrowthofMRSA.Noneofthepatienthadleucocytosis.ESRwasraisedin6patientswithmeanbeing34.42±21.57.CRPwasraisedin2patientswithmeanbeing26.55±95.

During3monthsfollowupvisit,only1patientwithpathologicalfracturewithchronicosteomyelitisoffemurhadpersistentpusdischargealongwithpersistentlocalriseoftemperatureandpositivepuscultures.Noneofthepatientshadleucocytosis.ESRwasraisedin3patientswithmeanbeing19.66±14.97.CRPwasraisedin2patientswithmeanbeing4.21±3.97.Timetounionwas2monthsin3patients,3monthsin2patients,4monthsin1patient,6monthsin1patientand2patientsalreadyhadmalunionatthetimeofpresentation.Amongst2patients,1withoperatedcaseofcompoundfractureofshaftofrighttibiaandfibulawithtibiainterlocknailin-situhadpusdischargewithnon-unionwhileanotheronewithoperatedcaseofcompoundfractureofshaftofrightfemurwithexternalfixatorinsituhadpusdischargewithnon-union,antibioticimpregnatedcementedKnailwasremovedandIlizarovringfixatorwasappliedduetointractableinfection.Apatientwhopresentedwithcompoundsegmentalfractureofshaftofrighttibiaandfibulawithboneloss,Masquelettechniquewasdoneduetodevascularisedmiddlefragment.

Exchangenailingwithremovalofknailwasdonein9patientswhenalltheclinicalandlaboratoryparametersbecamenormalfor2consecutivefollowupwithin1monthinterval.1patientdevelopedabscessoverdistallegduringthe2monthfollowupperiod whichwasthenmanagedwithincisionanddrainage.

Table6:- Clinic-Laboratoryparameters.

	Preoperative		**1month**		**2months**		**3months**	
	Number	%	Number	%	Number	%	Number	%
Pusdischarge	11	91.66	4	33.33	2	16.66	1	8.33
Localriseoftemperature	12	100	5	41.66	3	25	1	8.33
Pusculture	8	66.66	5	41.66	2	16.66	1	8.33
Leucocytosis	3	25	0	0	0	0	0	0
↑ESR	9	75	8	66.66	6	50	3	25
↑CRP	9	75	4	33.33	2	16.66	2	16.66

Figure 1:- Pre OperativeX-ray.

Figure 2:- Intra Operative Image Showing Pus.

Figure 3:- Post Operative X-ray.

Figure 4:- 1.5 Months Follow Up.

Figure 5:- X-ray After Exchange Nailing.

Figure 6:- 5 Months Follow Up X-ray.

Discussion:-

Thetreatmentofinfectednon-union,pathologicalfracturesduetoosteomyelitisandcompoundfractureswithgrosscontaminationrequiresprocedurestocontroltheinfectionandtoprovidestabilityinordertoachieveunion.Thereisnosingleuniversallyacceptedmodalityoftreatmen

tpresentlyavailableforthemanagementoftheseconditions.Traditionally,theseconditionshavebeenmanagedusingtwo-stepproceduretocontroltheinfectionfirstandsubsequentlytotreatthenon-union.

Antibioticcementimpregnatednailsdeliverahighconcentrationofantibioticsatthelocalsitewithoutcausinganysystemictoxicityalongwithprovidingstabilityatthefracturesite,therebyconvertingatwo-stageprocedureintoasinglestageprocedure.Antibioticcementnailsalsohelpavoidcomplicationslikepinsiteinfections,jointstiffness,musclecontracturesasthepatientcanbemobilizedearly.InfollowingtheinitialreportbyPaleyandHerzenberg[8]in2002,manyresearchershaveproducedgoodresultsusingthisprocedureforthetreatmentofinfectednon-union.PaleyandHerzenbergstudiedasmallsampleofninecasesandreportedinfectioncontrolinallthecases.ThonseandConway[10]in2007publishedastudywithalargesamplesizeof52patientsandreportedinfectioncontrolin85%ofthepatients.Qiangetal[9]reportedinfectioncontrolledin17of18(94.4%)cases.Inourstudy,infectionwascompletelyeradicatedin9outof12cases(75%).Similarresultssuggestthatantibioticcementimpregnatednailingisdefinitelyagoodmeantoeradicateinfection.

Conclusion:-

Antibioticcementimpregnatednailingisasimple,economical,andeffectivesinglestageprocedureforthemanagementofinfectednon-union,pathologicalfracturesduetoosteomyelitisandcompoundfractureswithgrosscontamination.Itisadvantageousoverexternalfixators,asiteliminatesthecomplicationsofexternalfixatorsandhasgoodpatientcompliance.Themethodutilizesexistingeasilyavailableinstrumentationandmaterialsandistechnicallylessdemanding,andthereforecanbeperformedatanygeneralorthopaediccentre.

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