

**ANALYSIS OF THE PERIOPERATIVE MORBIDITY AND
MORTALITY ASSOCIATED WITH BILATERAL SEQUENTIAL
TOTAL HIP OR KNEE ARTHROPLASTY (2013-2019)**



A dissertation submitted to The Tamil Nadu Dr. M.G.R. Medical University in
partial fulfilment of the requirement for the award of
M.S. Branch (Orthopaedic surgery degree) 2017-2020

**REGISTRATION NUMBER:
221712401**

CERTIFICATE

This is to certify that this dissertation:

**“ANALYSIS OF THE PERIOPERATIVE MORBIDITY AND
MORTALITY ASSOCIATED WITH BILATERAL SEQUENTIAL
TOTAL JOINT (HIP AND KNEE) ARTHROPLASTY” (2013- 2019)**

Is an original work of research done by Dr. ANDREW ISAAC CHRISTUDOSS
in partial fulfillment of the requirement for the award of M.S. Branch
(Orthopaedic surgery degree) 2017-2020

Prof. Dr.Pradeep Mathew Poonnoose

Professor and Head of the Department of Orthopaedic Unit -2

Christian Medical College, Vellore.

CERTIFICATE

This is to certify that this dissertation:

**“ANALYSIS OF THE PERIOPERATIVE MORBIDITY AND
MORTALITY ASSOCIATED WITH BILATERAL SEQUENTIAL
TOTAL JOINT (HIP AND KNEE) ARTHROPLASTY” (2013-1019)**

Is an original work of research done by Dr. ANDREW ISAAC CHRISTUDOSS

in partial fulfillment of the requirement for the award of M.S. Branch

(Orthopaedic surgery degree) 2017-2020

Prof.Dr.Vinoo Mathew Cherian

Professor and Head of the Department of Orthopaedics and Unit-1

Christian Medical College, Vellore

CERTIFICATE

This is to certify that this dissertation:

**“ANALYSIS OF PERIOPERATIVE MORBIDITY AND MORTALITY
ASSOCIATED WITH BILATERAL SEQUENTIAL TOTAL JOINT (HIP
AND KNEE) ARTHROPLASTY” (2013-2019)**

Is an original work of research done by Dr. ANDREW ISAAC CHRISTUDOSS

in partial fulfillment of the requirement for the award of M.S. Branch

(Orthopaedic surgery degree) 2017-2020

Prof. Anna.B. Pulimood

Principal

Christian Medical College, Vellore

DECLARATION

This is to declare that this dissertation:

“ANALYSIS OF PERIOPERATIVE MORBIDITY AND MORTALITY ASSOCIATED WITH BILATERAL SEQUENTIAL TOTAL JOINT (HIP AND KNEE) ARTHROPLASTY” (2013-2019)

Is an original work of research done by Dr. ANDREW ISAAC CHRISTUDOSS

in partial fulfillment of the requirement for the award of M.S. Branch

(Orthopaedic surgery degree) 2017-2020

Candidate:

Dr. Andrew Isaac Christudoss

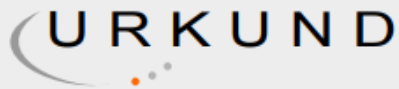
REG NO: 221712401

Post graduate Registrar-2017-2020

Department of Orthopaedics

Christian Medical College, Vellore

PLAGIARISM CERTIFICATE



Urkund Analysis Result

Analysed Document: Thesis on Bilateral sequential arthroplasty-Morbidity-21.10.2019
plagiarism.docx (D57342271)
Submitted: 10/21/2019 7:59:00 AM
Submitted By: andy.isaac90@gmail.com
Significance: 5 %

Sources included in the report:

<https://www.ncbi.nlm.nih.gov/pubmed/17545424>
<https://www.wjgnet.com/2218-5836/full/v7/i3/195.htm>
<https://www.healio.com/orthopedics/total-joint-reconstruction/news/print/orthopedics-today/%7B313c2d67-5d75-4515-ac51-983629b697e6%7D/proper-patient-selection-key-to-simultaneous-bilateral-total-joint-arthroplasty>
<https://www.ncbi.nlm.nih.gov/pubmed/9526210>
https://www.researchgate.net/publication/327430567_Does_simultaneous_bilateral_total_joint_arthroplasty_increase_deep_inf

ACKNOWLEDGEMENTS

This dissertation would be incomplete without expressing gratitude to the people involved in this study.

I am grateful and fortunate to have been able to study and learn in Christian Medical College and Hospital, Vellore over these last 3 years and I thank God for this opportunity.

First and foremost I wish to express my deep sense of gratitude to my Guide, Prof. Pradeep Mathew Poonnoose-Head of the Orthopaedic unit -2 who has been the most inspiring, supportive and approachable teacher throughout this phase. From the start of this study, he has been the driving force with his enthusiasm, inputs, timely suggestions, gentle reminders, prompt corrections and replies. I am indebted to him for mentoring me and for helping me finish this dissertation on time.

I would like to thank Prof. Anil Thomas Oommen who was a Co- investigator in the study for letting me include his patients in the study and for his valuable inputs throughout the course of the study.

I am grateful to Dr.Jerry George and Dr.V.J Chandy, who helped me start the study in the right direction and for their timely encouragement.

I thank Prof. Vinoo Mathew Cherian, the Head of the department, for being supportive and encouraging me to finish on time and for giving me time to complete this work.

I also am grateful to the Professors and Consultants from other units, for giving me time for data collection, IRB submission and for their valuable input and discussion regarding my thesis.

I thank Dr.Antonisamy, Head of Biostatistics and Mrs.Gowri who were the Statisticians for this study, for their time, patience, accurate analysis and prompt work which helped me finish the study on time.

I wish to express my thanks to the Principal and the management of CMC, Vellore for providing necessary facilities and financial assistance through the Institutional Fluid Research Grant for carrying out this work.

I would like to thank Mr.Muthu from the Medical Records Department who solely helped me to get all my 259 charts from the racks.

My thanks are due to my parents Drs.Ezhil and Pamela Christudoss and brother Dr.Joshua for their unwavering encouragement, support and strength during this study

Last but not the least my heartfelt gratitude is due to my wife Dr.Karuna for her immense support, critical suggestions and constant encouragement.

INDEX

1. Introduction-----	(1-9)
2. Aims and Objectives-----	(10-12)
3. Review of literature-----	(13-37)
4. Methodology-----	(38-48)
5. Analysis and Results-----	(49-74)
6. Discussion and conclusion -----	(75-89)
7. Limitations and strengths -----	(90)
8. Bibliography and Annexure(1-3)-----	(91-115)

INTRODUCTION

Total hip and knee arthroplasties are well established safe surgical procedures and are one of the commonest major orthopaedic procedures worldwide that provide pain free, mobile and functional joints in cases of advanced arthritis due to any reason. The number of total hip and knee arthroplasties performed worldwide has been on a rapidly increasing trend, the rate of primary THR(Total hip replacement) per 100,000 persons increased by 16% and the corresponding rate of primary TKR(Total knee replacement) increased by 42% during the 14-year period(1,2). Similar is the trend in prevalence of hip and knee arthroplasties in India(3) and the same is reflected in the number of surgeries performed at our institution.

Total joint arthroplasty of hip and knee have however, not been free of morbidity. There has been an ever prevalent concern about the risk of complications associated with simultaneous bilateral arthroplasties ever since they were performed from the 1960's and the decision to stage it or do it simultaneously has been hotly debated. The choice between unilateral, simultaneous bilateral and sequential bilateral arthroplasty is made depending on the diagnosis, the extent of involvement of the concerned joints and the financial, logistical feasibility for the patient and the medical fitness of the patient. The following are the definition of the three terms which have sometimes been interchangeably used in various papers.

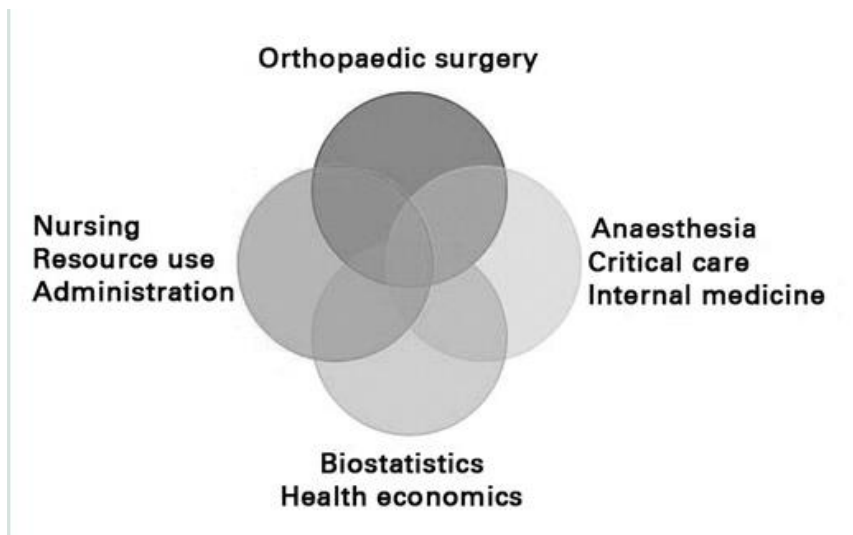
Staged Bilateral arthroplasty: When two of the same joints, either hip or knee operated one after another under two different anaesthesia on two different days, either in the same admission or 3 months or 6 months apart or a year apart.

Simultaneous Bilateral arthroplasty: When two of the same joints are replaced under the same anaesthesia with two teams operating at the same time.

Sequential Bilateral arthroplasty: When two of the same joints either the hip or the knee are replaced under the same anaesthesia one after the other by one team of doctors.

In this study we will be primarily discussing about sequential bilateral arthroplasty for hips and knees.

There are no absolute indications for a Sequential bilateral joint surgery, Patient preference is important. Patients who desire a single period of anaesthesia, hospitalization and recovery are more amenable to having both hips and knee done simultaneously. The Surgeon, Medical Consultant, and Anaesthesiologist must agree that the patient is healthy enough to undergo the surgery. There has to be collective decision taken by the teams working together when executing simultaneous surgeries as suggested by this Venn diagram.



.Picture no: 1(Eric .I.Hume)

1: Team based approach in bilateral Sequential joint surgeries.

The knee consensus group (4) had stated that if there is a concern between the surgical condition of the patient and the medical condition of the patient the medical condition should get more preference.

1. Safety of Simultaneous Joint Replacements:

There has been contradicting reports for the safety profile of bilateral simultaneous arthroplasties. Proponents of this procedure point out potential advantages including single anaesthesia, reduced hospital stay, lower overall costs and a single rehabilitation phase(5,6). However, other studies have shown increased risk of complication associated with simultaneous bilateral total joint arthroplasty; the commonly cited complications include increased blood transfusion requirement, higher risk of pulmonary embolism, cardiac and other systemic complications -

Memtsoudis et al- 12.2%,Pavone et al-21.8 % , Kiran et al-18%,Adili et al-26.8% and Hutchinson et al-7.53% , Keith Berrend et al-71.5%. Studies showed that the percentage of major complications ranged from (7.5%-71.5%).

81% of participants in the consensus meeting in 2013(4)agreed that BTKAs(Bilateral total knee arthrplasty) are more invasive and complex procedures associated with increased risk for perioperative adverse events compared with UTKA(Unilateral total knee arthroplasty) in an unselected group of patients.

However, other studies have shown a lower complication rate with simultaneous replacements. In a meta-analysis of 18 studies comparing simultaneous and sequential bilateral total knee arthroplasty, Hussain et al(7) reported that the complication rates were similar in the two groups.

Complication rate	simultaneous	Staged
Postoperative complications (n, %)	14 (25.9%)	8 (20.5%)
DVT	5 (9.3%)	3 (7.7%)
Pulmonary emboli	0	1(2.5%)
Hematoma (n, %)	6 (11.1%)	4 (10.3%)
Wound healing problems	3 (5.6%)	1 (2.5%)
Peri-prosthetic infections (n, %)	0	0
Perioperative mortality	0	0

Jong et al (8), reported that there was no significant difference in complication rates between unilateral and simultaneous bilateral total knee arthroplasty,1.4% in the simultaneous group and 5% in the staged group, however blood requirement was more in simultaneous(3.02 units) vs. 1.90 units in the sequential.

For hip arthroplasty the risk of postoperative complications in sequential arthroplasty is approximately 1.3 times more frequent than with unilateral total hip arthroplasty (9).

Based on the contradiction in reports, Sequential bilateral arthroplasty has generally been recommended only for young and healthy individuals and one needs to carefully consider when indicated in patients with heart disease, pulmonary insufficiency, or diabetes, and it is generally accepted that it is contraindicated in patients with a documented patent ductus arteriosus or septal defects (9).

Due to this discrepancy in safety, many surgeons around the world choose to play it safe and offer a staged approach. A study conducted by K.Kellieitch et al in Ontario in 2005 found that, 65% surgeons preferred staged approach (28% 3 month and 37 % 6 month interval),29 % performed either sequential or simultaneous (10).

2. What is our experience with sequential joint surgeries?

At our institution, a previous audit done five years back in 2010-2011 by Viswanath et al in an unpublished data from MS Orthopaedic thesis in 2010-2011 from patients operated in all the 3 units, wherein they studied 95 cases of bilateral sequential hip or knee arthroplasty showed a high rate of complication as follows.

1 postoperative death following a bilateral sequential total hip arthroplasty for inflammatory arthritis of the hip due to pulmonary embolism,54.8% had intraoperative complications with bilateral sequential arthroplasty(significant fall in

blood pressure(>20% drop from average blood pressure), drop in saturation(<90% or requiring any intervention) and arrhythmias) ,46.3% needed intensive care support in the immediate postoperative period for various complications and postoperative monitoring and 17.9%(17/95) had major postoperative complications,17.95%(17/95) had minor postoperative complications associated with sequential bilateral arthroplasties raising concern.

Major complications	No of patients
Cardiovascular event	5(5.2%)
Severe hypotension	2(2.125%)
Femoral nerve palsy	1(1.06%)
Cerebrovascular event	2(2.1%)
DVT(Popliteal vein thrombosis)	2(2.125%)
Acute kidney injury	2(2.125%)
Hip dislocation-post op	1(1.06%)
Deep wound infection	3(3.375%)

Minor complications	No of patients
Wound break down	9(9.5%)
Electrolyte imbalance	5(5.3%)

As a result, several changes were made in management of these patients:

- 1) Use of tranexemic acid for reducing blood loss

- 2) Release of tourniquet before closure and achieving good haemostasis.
- 3) Preoperative and perioperative pain control; with cocktail injections and regional blocks- to reduce pain and enable early mobilization,
- 4) Presence of 2 senior surgeons for every surgery, surgeons remaining till skin closure,
- 5) Routine use of anticoagulants postoperatively till satisfactory ambulation along with mechanical aids to prevent DVT,
- 6) Early mobilization from postoperative day 2.

3. Why has bilateral simultaneous/sequential arthroplasty become the forefront of discussion all over the world?

With recent news of death of a couple of patients following a bilateral sequential surgery, the government and various institutions around the globe are pushing to propose a criteria for good patient selection and hospital requirements for sequential arthroplasty to be done.

At a time when the nation's agenda is focused on health care reforms, several key issues are closely connected including patient safety, risk stratification, and cost. Apart from internal institutional pressures to be accountable, Orthopaedic surgeons face numerous public, governmental and external pressures. In an ever changing politico-economic climate, finite resources the balance between cost and the infrastructure needed in order to reduce the risks, both in terms of morbidity and mortality inherent in simultaneous/sequential joint replacement surgery.

We as a department have been performing simultaneous surgeries for over a decade and after certain changes were introduced, it has been observed that the perioperative morbidity, blood transfusion rates, and ICU(Intensive care admission) admissions have drastically decreased over the last 5-6 years to lower than 5% and we have had excellent results with bilateral sequential joint replacements, even high risk patients with appropriate preoperative stabilisation have done very well.

Since available evidence is plagued by a strong risk of bias, we found it necessary to perform a thorough analysis of this controversial information and to come up with the best strategy to provide patients with a prompt relief of symptoms without increasing the risk of the complications. Therefore, the aim of the present study is to determine which patients are suitable for a simultaneous bilateral hip arthroplasty, hence we aimed at studying the perioperative morbidity and mortality of these patients undergoing a Sequential joint surgery.

AIMS

AND

OBJECTIVES

AIM:

- To study the intraoperative and early postoperative morbidity and mortality associated with simultaneous bilateral arthroplasties of the hip and knee.

OBJECTIVES:

Primary objectives:

- To determine the incidence of perioperative – (intraoperative and early postoperative (till the time of discharge) complications after sequential bilateral total joint arthroplasty of the hip and knee, in terms of:
 - Local complications including haematoma, wound break down, infection, periprosthetic fractures and dislocations.
 - Systemic complications including myocardial infarction, pulmonary embolism, pneumonia, deep vein thrombosis urinary retention, paralytic ileus and CNS infarction.
 - Blood loss as indicated by drop in Haemoglobin
 - Blood transfusion rates
 - ICU admissions
 - Mortality
 - Readmission Rates

Secondary objectives:

- To analyse the efficacy of changes made in the Unit policies and protocols implemented following an audit done six years back on the complications of arthroplasties.
- To identify predictors of morbidity in patients undergoing bilateral total hip and knee arthroplasty.

LITERATURE REVIEW

1. BILATERAL SEQUENTIAL KNEE ARTHROPLATY:

Ever since bilateral sequential knee and hip replacements have been performed since the 1960's till date the safety of simultaneous bilateral total knee replacement still remains controversial, with some studies showing high rate of complications including death, while others have reported no increase in complication rate as compared to unilateral or staged. The 3 most recent meta-analyses comparing morbidity and mortality following BSTKA (Bilateral simultaneous total knee replacement) (Restrepo et al. 2007, Fu et al. 2013, Husain et al. 2013) all concluded that BSTKA carries a higher risk of postoperative mortality. Conclusions on postoperative complications are less sure, as meta-analyses by both Hussain et al. (2007) and Fu et al. (2013) found similar rates of thromboembolic and cardiac complications and also infections, while Restrepo et al. (2007) found a higher risk of cardiac and pulmonary complications following BSTKA than after staged procedures.

When both knees have failed conservative management and require joint replacement, the question remains: should bilateral TKAs be performed simultaneously, sequentially or staged. When both knees are affected by end-stage osteoarthritis, replacement of 1 of the 2 joints does not fully restore a patient's function, and the patient remains significantly debilitated. 81% of participants of the knee Consensus group (4) agreed that if a patient is not deemed a candidate for same-day BTKAs, a second TKA should be scheduled no sooner than 3 months after the first.

a) Rationale behind a single stage Bilateral Knee Arthroplasty?

Knee osteoarthritis was traditionally considered an 'asymmetric' disease. Cross sectional studies have shown that bilateral knee pain is a frequent problem in the Population 87% of patients awaiting total knee replacement (TKR) have radiological evidence of osteoarthritis on the other side(11). The Study also showed that at any point in time, incidence of bilateral joint disease is 26% and with time the numbers increase exponentially, 52% at 5 years and (70%) at the 12 year follow up. It was also seen that 10% of patients who had a total knee required the second side to be operated by 1 year(11).

The number of total knee arthroplasties (TKAs) performed in the United States is projected to reach 3.48 million per year by 2030, representing a 675% increase from 2005 (12). To ensure these rising needs are met, the role of simultaneous-bilateral surgery will likely expand in the treatment of patients with bilateral symptomatic arthritis. However, an accurate and up-to-date understanding of their risks is required if simultaneous-bilateral arthroplasties are to be considered over staged arthroplasties or unilateral surgeries(12) and adequate resources and standardisation be put into place.

b) Criteria for selection for bilateral simultaneous total knee arthroplasty-

Who is an ideal candidate?

There have been broad guidelines which have been laid for patient selection. Researchers from Hospital for Special Surgery which is a frontrunner in arthroplasty looked at the risks of postoperative complications among patients undergoing either single-stage bilateral TKR or unilateral TKR and came up with the following guidelines.

The following were their guidelines for patient selection.

Absolute exclusion from bilateral simultaneous or sequential knee arthroplasty.

- 75 years or older, ASA class III, Active ischemic heart disease, Poor ventricular function, Oxygen-dependent pulmonary disease.

Increased risk for perioperative complications:

-Insulin-dependent diabetes, Renal insufficiency, Pulmonary hypertension, Steroid-dependent asthma, Morbid obesity, Chronic liver disease, Cerebral vascular disease.

The consensus group 2013 put forth the following exclusion criteria.(4)

Age>75, ASA 3 and above, Active Ischemic heart disease (positive stress test or angina equivalents), Decreased left ventricular ejection fraction <50%, Active pulmonary disease-Pulmonary artery hypertension, oxygen dependent patients, steroid dependent asthma, Exercise limiting COPD, Morbid obesity BMI >40, Renal insufficiency creatinine>1.6, Poorly controlled diabetes mellitus, Cerebro vascular

accident or a previous history of stroke, Chronic liver disease-Childs score B or greater and Major peripheral vascular disease –with presence of stents.

The ideal candidates for bilateral knee arthroplasty in simple terms should be patients who are middle aged (40-65), who do not have any life threatening co morbidities, not overweight are active and have a general good physical condition prior to surgery. These patients may have the best benefit of having a bilateral knee or hip replacement without high risk for perioperative complications. Occasionally if the patients insisted, with knowledge of risks associated, we did perform bilateral arthroplasty in a selected few.

c) Advantages of bilateral sequential knee arthroplasty:

Various advantages of undergoing a simultaneous knee arthroplasty for a bilateral knee disease have been stated.

In 1997 Ritter et al(13)in a retrospective review found that, patients receiving simultaneous bilateral TKA return to full function earlier, experience less total anaesthetic exposure and the procedure is more cost-effective. He showed that patients undergoing simultaneous procedure had lower rate of wound complication and nosocomial infections and had a similar 2 year mortality rate of 4 %.Reuben et al in his study in 1998 showed that a simultaneous or a sequential surgery was more cost effective as compared to a staged procedure. Among knees he stated that costs were 36% less compared to a staged procedure(14).

In a Systematic analysis conducted by Fu et al in 2013(6) they found the following No significant difference was seen in regard to Neurological complications(1.01), deep-vein thrombosis (1.07), cardiac complications(0.52), superficial infection(0.92).The revision rate(0.48) and deep infection(0.52) were significantly lower in simultaneous surgeries.

d) Disadvantages of a bilateral sequential total knee Arthroplasty:

Despite being favoured in recent years with good evidence to suggest a significant decrease in perioperative morbidity and mortality for bilateral sequential knee arthroplasty even recent studies at good centres have showed evidences of complication and problems with simultaneous surgeries.

In a study at Hospital for special surgery T.PSulco et al 2017 did a retrospective review of 501 patients showed the following outcomes. There were arrhythmias pre in 5% of patients. Fat emboli were found in 3% and 2 patients (0.4%) had pulmonary emboli. The average units transfused was 2.6 units and allogeneic blood was required in 42%. There were 2 deep infections, 3 hematomas and 5 patients with delayed wound healing(15).

In a Meta-analysis conducted by Camilio et al in 2007(16) they showed that the prevalence's of pulmonary embolism (odds ratio = 1.8), cardiac complications (odds ratio = 2.49), and mortality (odds ratio = 2.2) were higher after simultaneous bilateral total knee replacement.

A Systemic review performed by Dong Fu et al in 2013(6) where eighteen retrospective comparative studies were included. Pooled results showed that the prevalence of mortality at 30 days postoperatively, pulmonary embolism, blood transfusion rate were significantly higher in simultaneous TKA group.

It was seen that, in studies published from the 1980's to 2005 comparing staged and simultaneous procedures , most studies showed a higher complication rate in bilateral simultaneous surgeries as opposed to staged surgeries as seen below.

Authors	Year	No of patients	No of knees	Conclusions
Gradilas and Vols	1979	81	122	Higher Rate of pulmonary embolism
Soudry et al	1985	230	304	Higher rate of DVT
Morrey et al	1987	877	1253	Higher rate of DVT
Lynch et al	1997	196	294	Higher cardiac complications
Lane et al	1997	200	300	Higher rate of cardiac complications

Dorr et al	2002	153	227	Higher rate of cardiac complications
Ritter et al	2003	3998	6200	Higher rate of mortality
Gill et al	2003	2848	3048	Higher rate of mortality

In summary, bilateral simultaneous /sequential surgeries have the following advantages in being more cost effective, shorter duration, single anaesthesia exposure and better functional outcomes and have also shown to have lesser revision rates.

However they also have shown to have some disadvantages like increased peri operative morbidity and mortality, wound complications, higher rate of DVT and cardiac complications.

2. BILATERAL SEQUENTIAL TOTAL HIP ARTHROPLASTY

Bilateral simultaneous total hip replacement was first reported by Charnley in 1967 and published by Jaffe and Charnley in 1971. Over the last three decades numerous surgeons have attempted to define the efficacy and safety of this procedure, compared with unilateral THR or staged bilateral procedures. Advocates of bilateral simultaneous THR suggest that it leads to an overall reduced hospital stay, shorter

anaesthetic and surgical times, faster rehabilitation and improved cost-effectiveness. It is contested, however that it is associated with an increased rate of complications, including deep-vein thrombosis (DVT), cardiopulmonary problems and increased medical morbidity making it an unfavourable procedure.

The main goal when treating these patients is to achieve the maximum efficiency without increasing the risk of perioperative complications, therefore, the decision regarding the best moment to operate the second hip comes into question. Although studies have addressed this topic, whether a simultaneous or staged surgery should be performed remains controversial just as we mentioned for total knees.

a) Indications and rationale for bilateral sequential Hip arthroplasty:

Disabling hip pain requiring total hip arthroplasty (THA) can have a variety of aetiologies, most of which like in Knee are found bilaterally. Bilateral hip disease can be caused by a single disorder or by a combination of two discrete processes. It has been estimated that 25% of patients with osteoarthritis requiring total hip replacement will need a bilateral replacement(17). Primary osteoarthritis (OA) of the hip, one of the most common disorders associated with severe hip pain and disability in the elderly especially in western countries, has a prevalence of 3.1% and occurs bilaterally in 42% of patients. Rheumatoid arthritis of the hip, although less common with an incidence of at least 0.2 per 1,000 per year, affects hips bilaterally in greater than 50% of patients. Other aetiologies of hip also present bilaterally. Hence screening of both hips is important and treatment for both hips at the same sitting for various reasons took center stage.

There are no absolute indications for a simultaneous surgery compared with staged procedures. The strongest indication is severe deformity in both hips in a medically fit patient. A relative indication is the presence of a condition that may retard the rehabilitation process. For instance, a contralateral contracture might produce a suboptimal result.

b) What is the patient selection criteria for hips?

Patient selection criteria is almost comparable to the one listed above for bilateral simultaneous total knee replacements. An important factor to keep in mind is the absence of tourniquet and the possibility of a higher amount of blood loss and blood product requirement and the process of reaming with higher incidence of fat emboli and cardiopulmonary problems.

Studies by Garland et al (18) and Rasouli et al(19) showed that the following were characteristics of patients with comparable outcomes to a staged hip arthroplasty.

1. Age <75
2. No active cardiovascular disease
3. No Rheumatoid arthritis
4. ASA<3

There is no evidence to say that patients who do not fulfil the above criteria have a safe outcome during bilateral surgery.

The available evidence supports the performance of simultaneous hip arthroplasty in selected patients (not older than 70-75 years, ASA 1-2, without cardiovascular co

morbidities) and suggests the avoidance of staged surgeries within the same hospitalization.(20)

The existence of a documented patent ductus arteriosus or septal defect, which would allow access of embolized material, such as fat droplets, to the arterial system and thus directly to the brain and other vital organs, is one of the few absolute contraindications to single stage bilateral THA.

c) Advantages of bilateral sequential hip arthroplasty

Advantages in bilateral simultaneous hip arthroplasty are similar to those in Knees. These have been stated in numerous studies over the past 30 years. The very first literature on bilateral simultaneous hip arthroplasty showed good outcomes and advantages with minimal added risks. Jaffe and Charnley in 1971 published a review of 50 consecutive patients in whom Charnley had done bilateral low-friction arthroplasty.

Salvati et al reviewed three groups of bilateral THAs done at the Hospital for Special Surgery from 1970 to 1976. Group I consisted of single stage procedures, group II of bilateral THAs done during the same admission, and group III of bilateral THAs done during separate admissions. He noted a marked reduction in cost associated with less time in surgery and decreased length of hospitalization. They did not find a higher complication rate within any particular group.

In a prospective study, Cammisa et al 1988 compared 23 patients who had single-stage bilateral THA with 12 patients who had unilateral THA. They concluded that perioperative morbidity of single-stage bilateral THA was no greater than that with unilateral THA with regard to cardiopulmonary function and overall clinical outcome(21)

Mark lorenze(17) reported a 24% decrease in costs of surgery and another study by Jeffrey et al(22) reported bilateral simultaneous sequential total knee arthroplasty was 36% less costly than 2 unilateral total knee arthroplasties.

A study by Shusaito et al(23) in 2010 comparing single stage hip replacements to a two stage replacements showed there is a significant decrease in hospital stay by 5-6 days when compared to two separate admissions in a two stage procedure.

Many recent studies have demonstrated similar rates of DVT, mortality, pulmonary embolism and infection between staged and simultaneous procedures(17,24,25).

Essentially the advantages as most authors describe are, single anaesthesia exposure, short hospital stay, less costs, decreased surgical time.

In recent years most authors have documented no difference in major complications and describe similar outcomes between staged and simultaneous hip arthroplasty.

d) Disadvantages of a bilateral sequential hip arthroplasty

The main concern associated with Simultaneous bilateral THA is the additional cardiopulmonary insult associated with embolization of the contents of two femoral canals (particularly with cement pressurization) at the same sitting. The additional impact on the three arms of Virchow's triad (stasis, hypercoagulability, and intimal injury) associated with the added surgical insult of two wounds and operations can lead to an increase in postoperative thromboembolic events.

In 1979, Charnley reported that the incidence of fatal pulmonary embolism after bilateral low-friction arthroplasty was 1.65%, and the incidence of nonfatal pulmonary embolism was 12.8%.

The second most commonly encountered problem is the blood loss and need for more blood transfusions and blood products.

In the audit done at our institution in 2010, the average number of blood transfused per case was 1.9 units for simultaneous total hip replacements.

Y-H KI showed that patients with bilateral THR required more blood transfusions and a longer hospital stay than those in the unilateral THR group(26).

Ritter and Randolph previously reported that simultaneous bilateral THA showed an increased incidence of deep venous thrombosis (DVT), pulmonary embolism, and myositis ossification, while the duration of hospital stay averaged 1 week longer and operative time and blood loss doubled as compared with patients who underwent a

single unilateral operation, he also showed an increased rate of both phlebitis and myositis ossificans in patients undergoing bilateral simultaneous hip surgeries(9).

The following are a list of recent and older studies comparing simultaneous to staged procedures over 25 years.

Study	No of Patients	Results
Quadri et al-2015	48	No difference
Gartland et al-2015	42238	Simultaneous surgery safe in young and healthy patients.
Rasouli et al-2014	16330	More complications in staged patients done in the same hospital admission
Johnston et al -2011	589	More complications in Simultaneous
Lindberg et al-2013	680	No difference
Aghayev et al-2010	1918	No difference
Hopper et al-2009	2092	No difference
Berend et al-2007	277	More complications in simultaneous
Bhan et al-2006	168	More bleeding in staged and more transfusion in

		simultaneous
Parvizi et al-2006	196	No difference
Alfaro-adrain et al-1999	202	No difference
Egglı et al-1996	255	No difference

As we can see, most of the studies report no difference between complications and outcomes between the staged and simultaneous groups and report simultaneous surgeries to be safe if the appropriate measure are taken in the peri-operative period and if the patient selection is good.

3. MAJOR COMPLICATIONS OF A SEQUENTIAL SURGERY:

a) Mortality:

The safety of bilateral simultaneous knee or hip replacement in terms of mortality has been extensively studied and is still debated with inconclusive results. Authors have studied 30-day, 90-day and 1 year mortality. However in our study we have studied early mortality following a bilateral simultaneous procedure in the same admission.

Gromov et al(27) in his study observed that the 90 day mortality was 0 % after a bilateral simultaneous procedure in a retrospective study of 284 patients.

Chua et al(28) 2018, in one of the largest studies of bilateral knee replacements of 36,000 cases, found the 30 day mortality to be 0.17% for bilateral simultaneous surgery. They found age and ASA grade to be higher in the simultaneous group. They reported a statistical difference between the simultaneous group and the staged 6 weeks to 3 months group.

In another large study by Sheth et al (29), in a study of 11,118 undergoing total knee replacement, they found early mortality to be 0.28% in simultaneous procedures and 0.1 in staged.

In a study done in our institution in 2010-2011 on bilateral simultaneous patients, of 95 patients one patient died due to massive pulmonary embolism.

In general the mortality in a simultaneous surgery is (0.25-0.3) % and is 0.15-0.20 in a unilateral surgery.

Age >75, rheumatoid, cardio pulmonary problems, ASA 3 or 4 were associated with a higher mortality.

b) Admission to Intensive care unit:

Patient safety is of utmost importance in an elective total joint replacement surgery. Being able to identify risk factors that might predict complications and intensive care unit (ICU) admission proves instrumental in reducing morbidity and mortality.

The rates of ICU admissions in simultaneous procedures have generally found to be much higher than the staged or unilateral. As most of the patient undergoing knee and hip replacements in the elderly age group with multiple co morbidities close

monitoring to avoid further complication is required. The most common indications for admission was found to be planned admission for monitoring, blood loss, hypotension and respiratory problems, need for oxygen and when more than 4 bloods transfused, postoperative MI and arrhythmia, especially in older age groups and those with higher risk factors, age > 75 years, body mass index > 35 kg/m², creatinine clearance < 60 ml/min, revision surgery, and prior myocardial infarction were all risk factors for ICU admission.

In a study done by Vishwanath et al in our institution on 95 cases, 44 patients (46.3%) of patients required postoperative monitoring in Intensive care unit with an average duration of stay of 2.4 days.

Our institution's and units experience with risk stratification and preoperative ICU triage has resulted in a reduction in planned ICU admissions and postoperative complications after a bilateral simultaneous joint surgery since 2013.

Studies done over the last 5 years have showed a significant decrease in the rates of intensive care admissions for bilateral simultaneous cases.

Parviziet al(30), reported 4% of those undergoing unilateral total hip arthroplasty (THA), and 12% of those having bilateral hip arthroplasty, may require unplanned ICU admission.

Kamath(31), in his study reported that rates of ICU admission in bilateral simultaneous hip replacement was 7.1%.

Bullock et al(32) showed the rates of admission of bilateral simultaneous knee replacements to ICU was 3.9% when compared to unilateral which was 0.59%.

C) Blood and Blood product transfusion:

Blood loss is one area of concern in patients undergoing bilateral simultaneous replacements more so in patients with co morbidities like cardiac disease, bleeding diathesis, renal disease, hypertension and inflammatory arthritis and patients requiring complex procedures with long duration of surgery.

Higher rates of transfusions have been described in bilateral simultaneous total hip vs. total knee which is done under tourniquet. In an audit conducted by Viswanath et al in our institution, he showed that on the whole a bilateral procedure on an average requires about 1.4 units of blood. In his study he also found that 56% of patients required 2 or more units of blood.

Rate of blood loss varies with duration of surgery, type of anaesthesia, type of protocols used, use of tranexemic acid, soft tissue handling(32).

Several ideas to reduce blood loss were also studied ,which included tranexemic acid, local infiltration, haemostatic matrix, fibrin sealant and tourniquets(33–35) which have significantly reduced the peri-operative blood loss and need for blood transfusions. Most of the authors from the consensus statement 2013 agreed that use of tranexemic acid has reduced perioperative blood loss and the need for blood.

Hafez et al(36), showed us in a study of 54 simultaneous total knee patients 16.6% needed blood transfusions and all were women.

The mean units transfused per patient in various studies have varied from 1 -3.5 units/case.

Problems with Increased rate of blood transfusions are increased in infections-PPJI, Immune reactions.

Allogeneic blood transfusion has been previously identified as an independent risk factor for infection after total joint arthroplasty. Increased levels of white blood cells (WBCs) may lead to immunomodulation (37).This above scenario is more relevant for bilateral procedure where the transfusion rates are higher and hence adequate measures ought to be taken and blood transfused only when required.

d) Infections:

As expectations after total joint arthroplasty are high, the occurrence of a peri prosthetic joint infection (PJI) can be overwhelming to the patient, consisting of serial interventions and antibiotic administration; they can have an enormous psychosocial and economic impact.

Despite our increased knowledge and available preventive measures, including prophylactic antibiotics, body exhaust suits, laminar air flow rooms, and so forth, PJI prevalence continues to range between 1% and 3%(38,39).

Houtari k et al showed the incidence of deep SSI in bi- and unilateral THAs and in bi- and unilateral TKAs was 0, 0.5, 1.0 and 0.9%, respectively. Following bilateral operations, four deep SSIs were detected, all from bilateral TKAs, three of which were on the second operative side(40).

Hooper et al (41), using registry data, reported that patient-reported infection rates for simultaneous and staged bilateral THA were 2.6% and 1.0% respectively.

Factors having a high predilection for infection:

1. Diagnosis-Inflammatory arthritis-use of immune modulators, immune suppressive therapy, dysplastic joints and severe deformities-Due to surgical time and poor soft tissue condition(42).
2. Use of allogenic blood transfusions.
3. Male Gender is also an independent risk factor(43),reasons unknown yet.

e) Cardiopulmonary complications:

Cardiac complication represents a major cause of morbidity and mortality after total joint arthroplasty. Most studies have showed the mean age in studies to be above 60, as a single stage surgery means longer duration, more blood loss, the fluid balance is altered and this can cause a massive strain on the patient's cardiopulmonary system taking into account their age. Cardiac complications are associated with increased hospital mortality, increased length of stay, increased non-cardiac events and increased health expenditure.

Cardiac complication can be myocardial infarction (MI)-STEMI/NSTEMI, angina equivalents or new-onset arrhythmia and heart failure. The consensus group Parvizi et al 2013 agreed that physicians and hospitals should consider using more restrictive patient selection criteria and exclude those with a modified cardiac risk index greater than 3 to mitigate the potentially increased risk(4)

Risks factors that increase the chance of having a cardiac event, age>80, prior cardiac disease, obesity .Feng et al had showed that single stage bilateral procedures had a higher chance of cardiac events when compared to unilateral arthroplasty (odds ratio - 1.57). Jenny et al(44) demonstrated 2.4% cardiac complications in their study, Restropo (16) in 2007 found the odds of having a cardiac event in a single stage surgery as compared to a unilateral procedure was 2.2 times higher.

f) Acute kidney injury (AKI) :

Perioperative AKI is associated with an increased morbidity and mortality in hospitalized patients. AKI can be renal, pre renal and post renal.

Post-renal AKI can be caused by urinary tract obstruction,pre-renal aetiologies are the most common postoperative causes of AKI, occurring secondary to decreased renal perfusion due to reduced cardiac output, hypervolemia, or fluid sequestration (45).

Ritter et al (46) proposed that the diminished intravascular volume, secondary to an inability of certain patients to manage the fluid shifts that occur during bilateral total knee arthroplasty, as one of the cause of hemoconcentration and subsequent elevation in serum creatinine(46).He reported an incidence of 11.2%.

Type of surgery, anaesthesia(spinal had less incidence of AKI),post-operative NSAID's, ACE inhibitors, older age, chronic kidney disease, cardiac disease, massive transfusion are all factors that can independently increase risks of AKI.

g) Pulmonary Embolism:

It is one of the most frequent causes of mortality in a single stage bilateral arthroplasty. Over the last 15 years, efforts have been made to reduce the incidence of venous thrombosis and PE by mechanical and pharmacological interventions and various protocols have been proposed.

In 1979, Charnley reported that the incidence of fatal pulmonary embolism after bilateral low-friction arthroplasty was 1.65%, and the incidence of nonfatal pulmonary embolism was 12.8%.

The phenomenon of fat embolism during THA was recognized early on during the history of THA. Some fat embolism occurred during the acetabular component seating, but most of the insult occurred during femoral component insertion. Fat emboli are believed to reach the systemic circulation either directly across the pulmonary capillary bed or indirectly via shunts (eg, a patent ductus arteriosus). In this way, embolic content can get directly to vital organs, such as the brain or the myocardium(47).

In a study done in 2014 by Yeager et al(48) he compared the incidence of pulmonary embolism in unilateral and bilateral THR and TKR. He found the incidence to be 1.87% in knees and 0.52% in hips.

Memtoudis et al(49) and Ritter et al(46) also looked at the rates of pulmonary embolism and found them to be 0.89 % and 0.9% respectively following bilateral total knee replacement.

h) Deep Vein thrombosis:

DVT is another potentially fatal post-operative complication. Despite many protocols and measures to prevent it, studies still show a higher incidence among single stage sequential surgeries. Hence risk stratification is important, to identify and treat those who are at a higher risk accordingly.

Factors that increase incidence of DVT- Previous history of thrombotic events, hypercoagulable states-Malignancy, oestrogen use, family history, smoking, hormone replacement therapy. In such cases the chemo-prophylaxis should be more aggressive and should be used in conjunction with mechanical measures.

Meehan et al (50) showed that 0.86% patients develop DVT in the first two months after a single stage procedure .

Liu et al in a study in 2019 on knees showed that in the simultaneous group there was 1.21 times more at risk of developing DVT than patients undergoing staged. Pulmonary embolism was the dominating cause (40%) of death in the simultaneous group and a considerably less common cause of death in the staged group suggests the increased embolic load during simultaneous causes increases the mortality(51).

Jenny et al (44) in a multicentre study on simultaneous knees showed almost 8% patients had DVT.

However many recent studies have showed no cases of DVT which could be due to their study population and their thromboprophylactic measures.

i) Neurological Complications:

A higher rate of postoperative neurological complications in the single stage bilateral group can be explained by a number of factors, including increased postoperative blood loss, increased hypoxemia and anaemia, increased need for analgesics, and increased fluid shifts and potential electrolyte imbalances.

However, neurological complications, together with the increased demand for nasal oxygen are linked to increased systemic dissemination of fat from the displacement of intramedullary fat intra operatively. Several authors have shown that bilateral procedures result in an increased prevalence of fat emboli with resulting neurological and pulmonary symptoms(51).

Our study in CMC done in 2010 had 2.1% patients having neurological complications.

Most studies do not show any difference between staged and simultaneous procedures.

J.Other complications:

Some other complications have been reported with bilateral simultaneous surgeries. Such as electrolyte imbalance –most commonly hyponatremia(49) with a relative risk of 2.2 over staged, gastro-intestinal problems like post-operative paralytic ileus and thrombophlebitis, myositis ossificans.

Respiratory Complications- Liu et al in his meta-analysis 2019(51), showed 1.6% had respiratory problems postoperatively like infections as opposed to 1.1% in the staged group.

Urinary Retention is another common post-operative complication and has been reported in literature, in a study in India in 2005 by Krisknakiran et al(52), he had 3 out of his 50 bilateral patients(6%) having post-operative urinary retention, but found no difference between simultaneous and staged.

Other not so commonly seen complications like dislocations, periprosthetic fracture have all been documented by some authors in small numbers less than 1% in most studies(44).

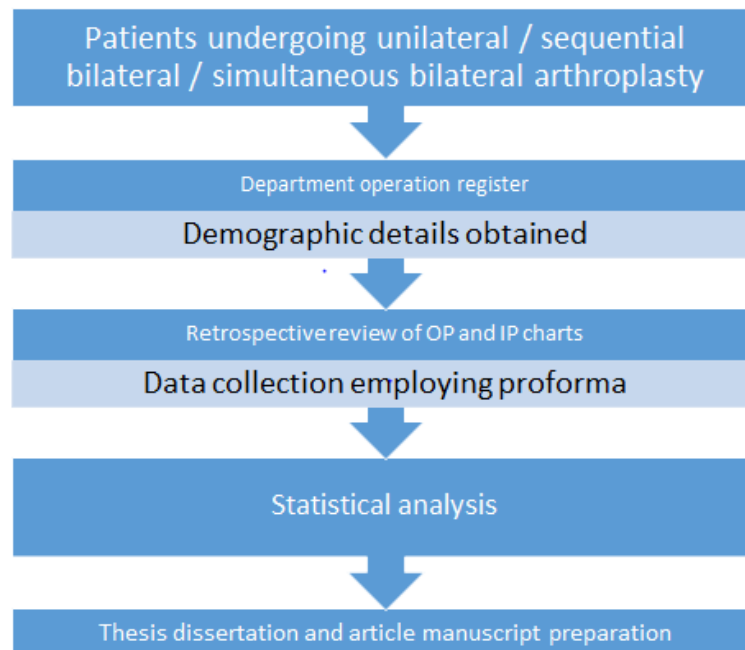
METHODOLOGY

a) Type of study:

The study was fully approved by the IRB of the institution. This is a descriptive study with a retrospective and a prospective arm-Bidirectional cohort.

Data was collected from discharge summaries, In - patient records, anaesthesia record, operation notes, nurse's records and Out - patient records, clinical workstation, and blood bank records.

b) Data Collection:



Data measurement:

- Incidence of complications: Number of individual and overall complications / total number of cases (Obtained from IP chart).
- Drop in Hb = (Last documented Hb before surgery) – (First documented Hb after surgery) - details from Clinical work station.

- Blood transfusions – details from Blood bank – number of units of blood transfused perioperatively.
- ICU admission: number of patients requiring ICU admission.
- Mortality: Number of deaths / total number of cases (obtained from IP chart).

c) Setting:

The study is in the setting of a single tertiary care hospital (CMC Vellore) at the Department of Orthopaedics – Unit 2. The study intends to include all patients who underwent sequential bilateral total hip and knee arthroplasty between 01/07/2013 to 15/7/2019.

d) Participants:

1. Inclusion criteria:

- Patients who underwent primary sequential bilateral total hip or knee arthroplasty, under Orthopaedics unit –II, between 01/07/2013 to 15/7/2019

2. Exclusion criteria:

- Patients who had a staged bilateral total arthroplasty

e) Rationale:

- The time frame is chosen after the point which changes were implemented in response to the previous audit.

f) Outcomes:

Each of the following will be determined for the entire sample, hip arthroplasty group, knee arthroplasty group:

- Incidence of intraoperative complication expressed as a percentage – incidence individually and combined.
 - Hypotension(MAP<50mm Hg) for ≥ 10 min
 - Desaturation <90% SPO₂ requiring intervention
 - Arrhythmia- Any arrhythmia causing decompensation of patient and warranting intervention.

- Incidence of local complications expressed as percentage – individually and combined including
 - Haematoma- Collection warranting evacuation
 - Wound break down-Discharge lasting >7 days with erythema requiring surgical action.
 - Infection-Documented culture from discharge that required a wash out.
 - Peri-prosthetic fractures-In the perioperative period, not related to any major trauma.
 - Dislocations-In the perioperative period, not related to a major trauma.
 - Deep vein thrombosis-Confirmed by colour Doppler.

- Incidence of systemic complications expressed as percentage – individually and combined including
 - Pulmonary embolism-Confirmed By CT- Angiogram
 - Myocardial Infarction-confirmed with ECG and enzymes
 - Pneumonia-Chest X-ray
 - Urinary retention/acute kidney injury-documented culture and creatinine
 - Paralytic ileus-Requiring decompression with an NG tube
 - CNS infarction-Documented by a CT Brain
 - Electrolyte imbalance

- Peri– operative blood loss as indicated by drop in Haemoglobin
- Percentage of ICU admissions following arthroplasty of hip or knee; the reason for and the duration of the same.
- Blood transfusion rates peri operatively-Mean Units used / Transfusion rate
- Mortality rate, expressed as percentage.
- Readmission Rates- as a percentage.

Sample size calculation

- Sample size calculation is based on the comparison of complication rate before the new protocol and assumed complication rate for the same.

- The percentage of complications as per our previous audit 18 % and the “expected” complication for the new protocol is assumed to be 8%. The sample size calculation is made for new proportion of 5%, with 5% error and 80% power and tabulated below.

Assuming our present complication to be 8%, we found the sample size to be 97.

- The following formula was used for the calculation.

$$H_0 : P = P_0 ; \quad H_a : P \neq P_0$$

$$n = \frac{\left\{ Z_{1-\alpha/2} \sqrt{P_0(1-P_0)} + Z_{1-\beta} \sqrt{P_a(1-P_a)} \right\}^2}{(P_a - P_0)^2}$$

P0= Previous complication proportion

Pa = Assumed complication rate

Statistical methods:

- The incidence was presented with 95% CI.
- The relation between the complication and the continuous variables were analysed using independent t - test/ Mann-Whitney u test (rank sum test).
- Chi-square test was used to compare the complication rate with categorical variables.
- Logistic regression analysis was performed to study the relationship between complications and risk factors.

Perioperative and surgical protocol

a) Preoperative work up:

1. Thorough physical and clinical examination and evaluation of co morbidities

2. Preoperative Investigations:

-Complete blood counts, creatinine and urea, blood borne virus screen, electrolytes, electrocardiogram, chest x-ray and a recent x-ray of the hip or the knees

3. Additional Investigations:

-HbA1C if diabetic

- ECHO- If there is any abnormal ECG or patients with cardiac history or symptoms –angina equivalents.

-Spirometry-For active pulmonary disease such as COPD and Asthma on steroids and activity restriction

- LFT, albumin –Chronic liver disease

b) Risk stratification:

Patients are worked up in detail and the following risks are assessed.

1. Risk assessment for risk of bleeding. (Standard/High)

2. Risk assessment for pulmonary embolism. (Standard /High)

Based on this, post operatively prophylactic anticoagulation is decided

1. If patient is at standard risk for both PE and major bleeding or at elevated risk for PE and standard risk for major bleeding

- Injection Clexane starting 12-24 hours postoperatively till 4th day until they ambulate well-once daily subcutaneous-Injection Clexane 20mg s/c

-Aspirin 75mg once daily for 4 weeks from day 4

-Mechanical prophylaxis.

2. Patients at standard risk of PE and are at an elevated risk of major bleeding

-Mechanical prophylaxis only

-No chemoprophylaxis

-If patient was preoperatively on Aspirin, restart same dose after drain removal.

3. Patient at elevated risk of both PE and major bleeding

-Discuss case with Haematology and take a call

-Mechanical prophylaxis.

Ward protocol for postoperative mechanical DVT prophylaxis

-Active Dorsiflexion and plantar flexion of ankle and toes and should be performed in sets of 10-20 every half an hour.

-Passive ankle dorsiflexion and plantar flexion with calf massage should be performed in sets of 10-20 every half hour.

-Patient made to sit up and out of bed 4-5 times a day.

*If patient is on Sulfasalazine –We omit use of Aspirin.

c) Intra Operative Protocol:

a) Anaesthesia-General, General+epidural, Spinal+epidural-Call taken by anaesthetist and patient.

b) Prophylactic antibiotics given 30min before shifting from the ward.

-Injection Cefuroxime 1.5gm stat Dose.

c) Injection tranexemic acid 500mg IV given before start of surgery along with the antibiotics and 2 other doses repeated at 6 hours and 12 hours.

d) Sterile Tourniquet at 350mmHg for both knees

e) Intraoperative blood loss estimated by surgeon and anaesthetist and intra operative arterial blood gas used to see if there is any blood requirement transfusion done if the maximum allowable blood loss has been exceeded.

f) The opposite knee is started just after the first knee is being closed, as for hips one side is closed and dressing done and the second side turned to lateral and freshly painted and draped.

g) One 10 g bore drain placed for knee and hips and fully charged.

h) One of the senior surgeon stays till wound closure

i) Patient monitored in the recovery room for a minimum of 1hour.

d). Postoperative Monitoring and ward management:

a) Assessed on arrival-Vitals

b) Postoperative haemoglobin on arrival in the ward and the following day if required.

c) Fluids for 6-12 hours

d) Strict Input and output charts

e) Catheterisation only if patient hasn't voided for 6-8 hours from the time of surgery. No use of red rubber Tube.

f) Dressing done only if soaked.

e) Patient is made to do static and dynamic quadriceps exercises on day 2 and allowed to sit in bed and stand.

f) Drain removed on third postoperative day and x-rays done and appropriate physiotherapy and ambulation initiated.

g) IV antibiotics stopped after 48hours, no oral antibiotics given.

h) Analgesia- intravenous paracetamol/Morphine PRN for the first 48hours, after which oral analgesics is continued.

i) Discharge-For bilateral hips Suture removal is done on the 10th post operative day and patient is discharged to follow up after 3 weeks.

For bilateral knees, patient is discharged at the end of 10days if the wound is healthy and suture removal done on 14th post operative day.

If any patient with inflammatory pathologies were on Disease modifying anti-rheumatic drugs prior to the surgery, a rheumatology opinion is obtained and the medications restarted after suture removal.

As most of our patients are in the Geriatrics population and perioperative medical problems are seen by the Geriatrics team.

**ANALYSIS
AND
RESULTS**

A.Descriptive characteristics

1. Number of Patients

A total of 259 patients (518 joint) underwent bilateral simultaneous joint replacement surgeries from 1.7.2013 to 15.7.2018 and fulfilled the study criteria.

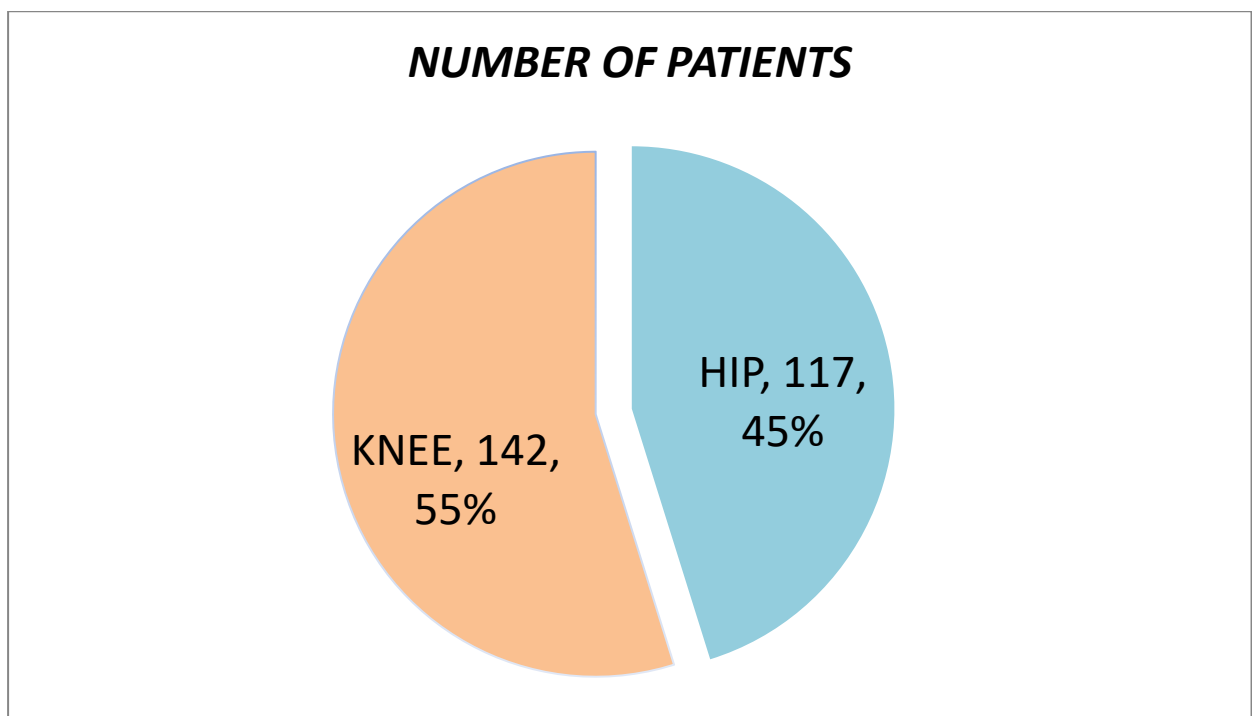


Figure no.1: Joint involved-Hip /Knee.

2. Year Wise distribution:

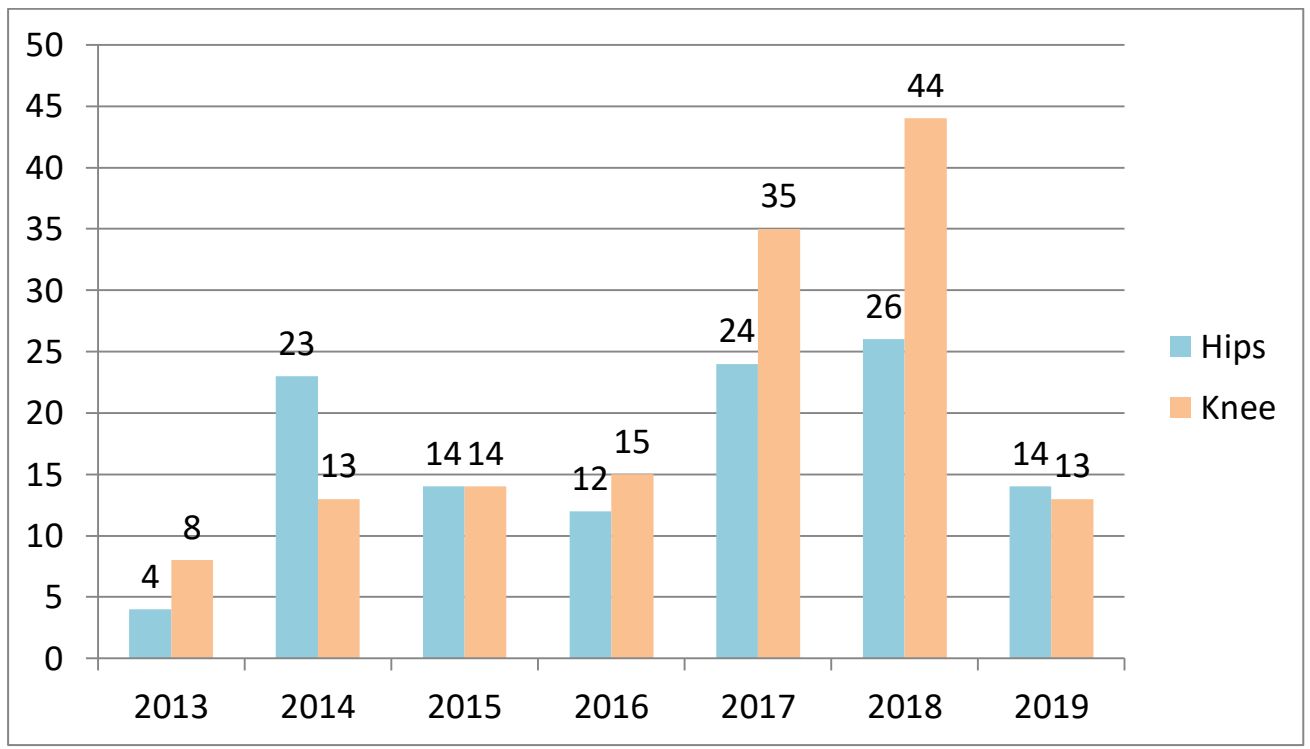


Figure no 2: year wise statistics

3. Age and Sex distribution:

3.1 Age:

The overall mean age was **47.5** years, with youngest patient being **13** and oldest patient being **84**.

Average age among bilateral Knee: **57.10 years**

Average age among bilateral hips: **35.5 years**

8 patients were above 75 years old

3.2 Sex:

In our study, we found that overall the number of male and female undergoing bilateral simultaneous surgeries were almost equal.

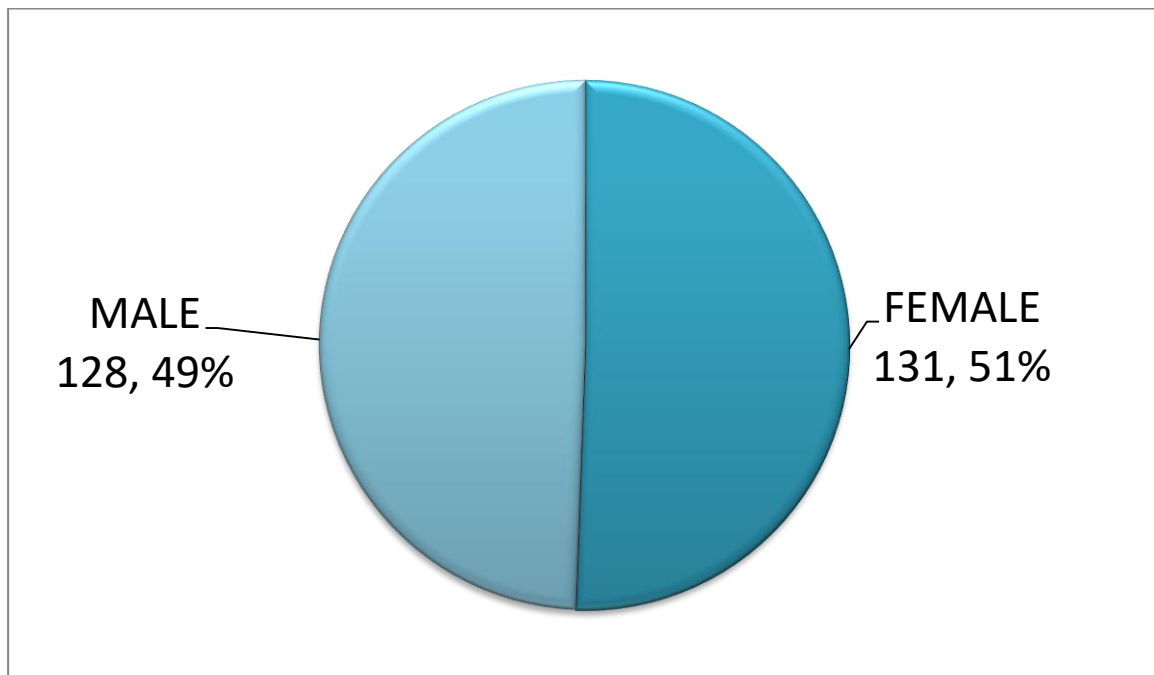


Figure no 3-Sex distribution

HIP:

Out of 117 hips, 80(68.4%) were **male**.

KNEE:

Out of 142 knees, 94(64.1%) were **female**.

4. DIAGNOSIS:

The total distribution including both hips and knee were as follows.

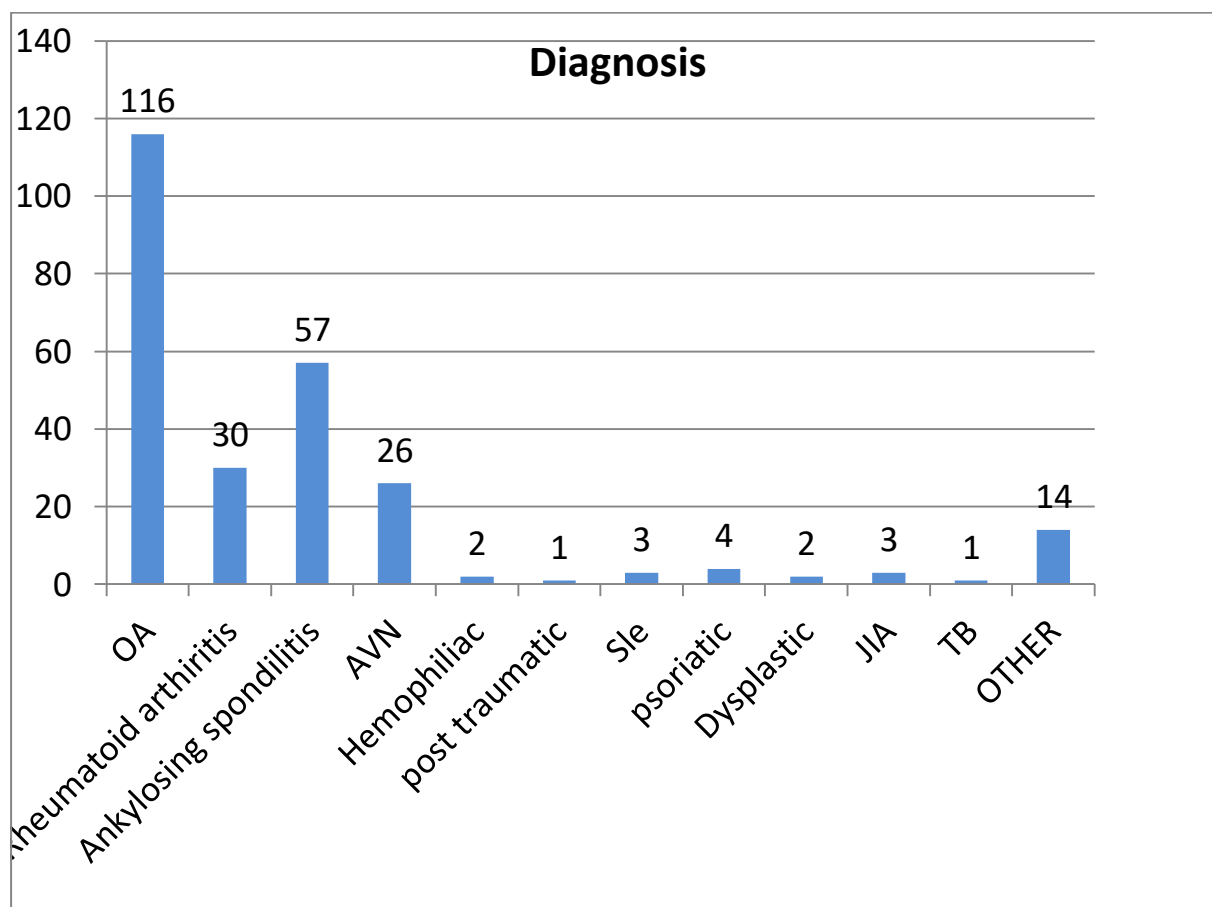


Figure no4: Diagnosis

111(42.8%) patients had a diagnosis of some form of inflammatory arthritis.

Inflammatory arthritis included- (Rheumatoid, ankylosing spondylitis, SLE, psoriatic, juvenile idiopathic arthritis and others which consisted of undiagnosed or rarer forms of inflammatory arthritis.)

116(44.7%) patients had a diagnosis of degenerative arthritis.

4.1 HIP:

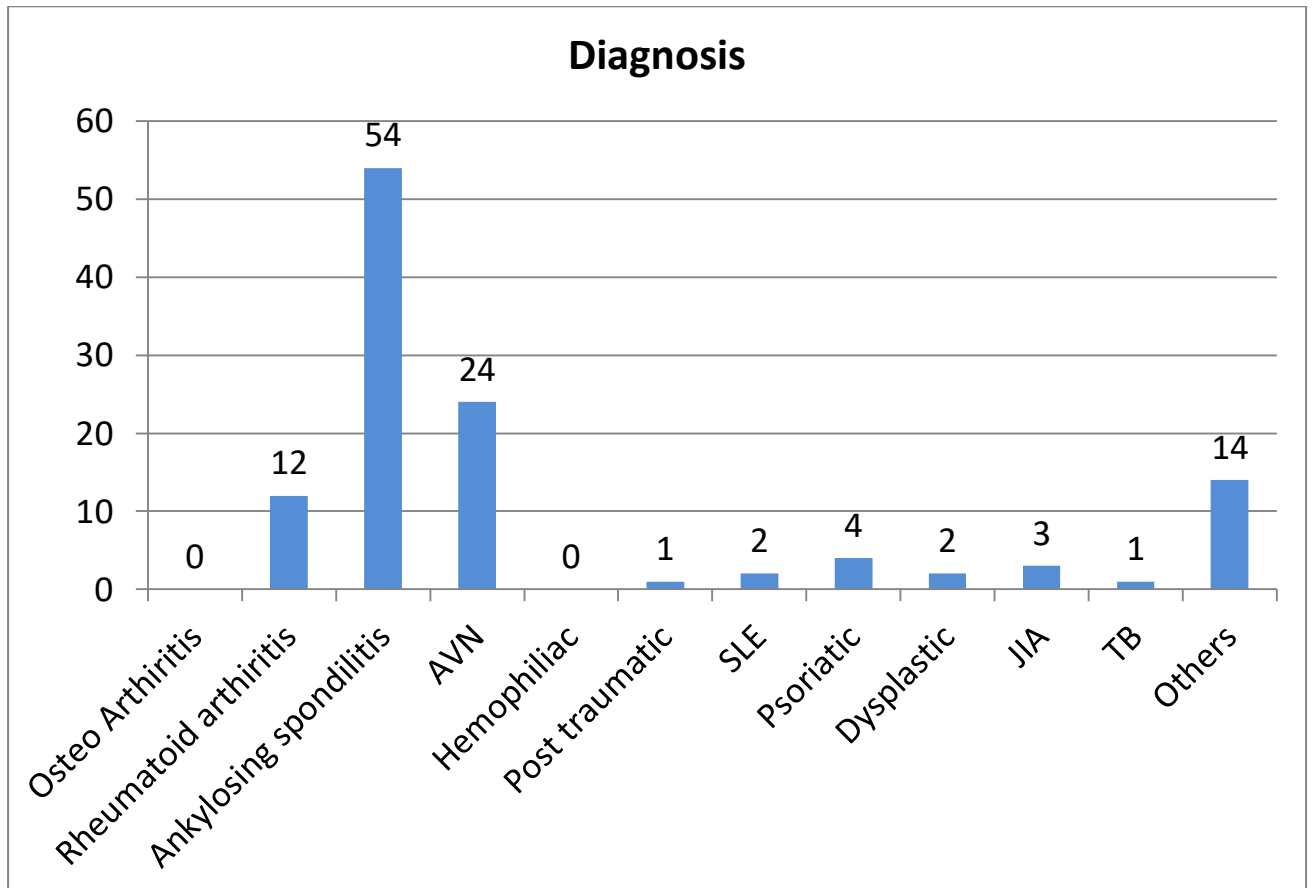


Figure no5: Diagnosis Hip

There were 0 patients who had a primary degenerative disease of the hip

89(76%) patients had **inflammatory arthritis** with **ankylosing spondylitis** being the most common **54(60.6%)** patients among the inflammatory.

4.2 Knee:

Among bilateral knees **116(81.6%)** had primary degenerative osteoarthritis.

18(12.6%) patients in our study among the knee joints had rheumatoid arthritis.

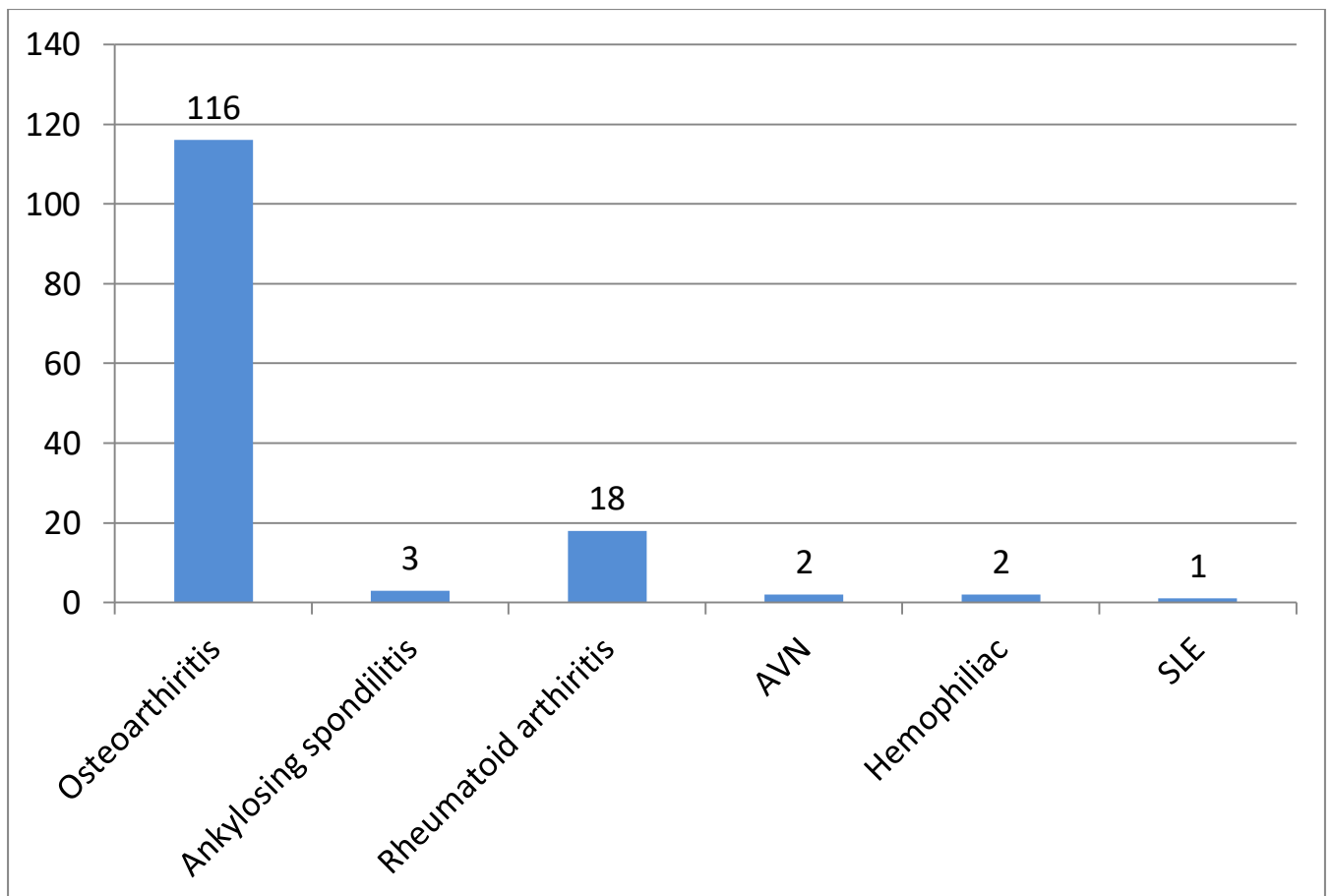


Figure no6: -Diagnosis Knee

5. MEDICAL CO MORBIDITIES:

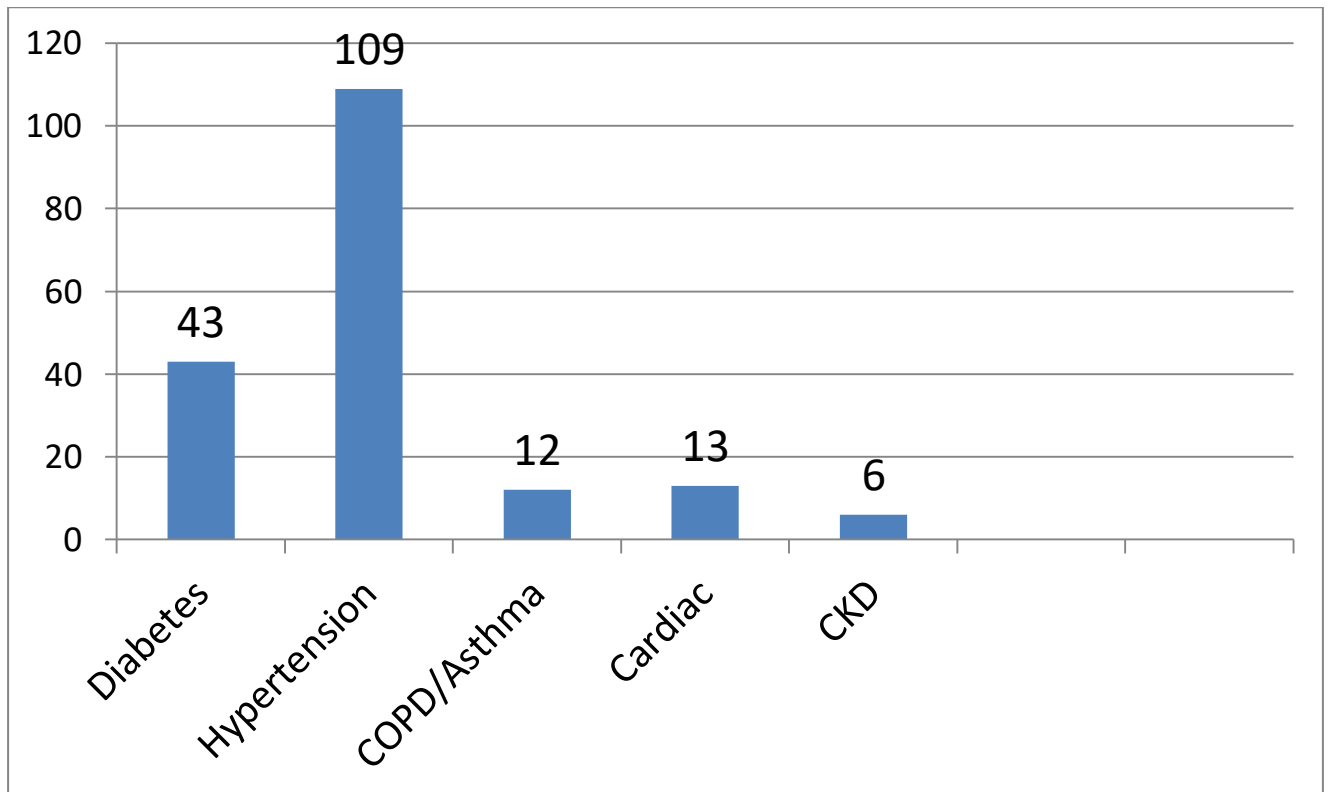


Figure no7: Medical comorbidities

Hypertension was the most common co morbidity **109(42.1%)**

45/259(17.39) % patients had **2 or more complications.**

50.58 % (131/259) patients had no complications.

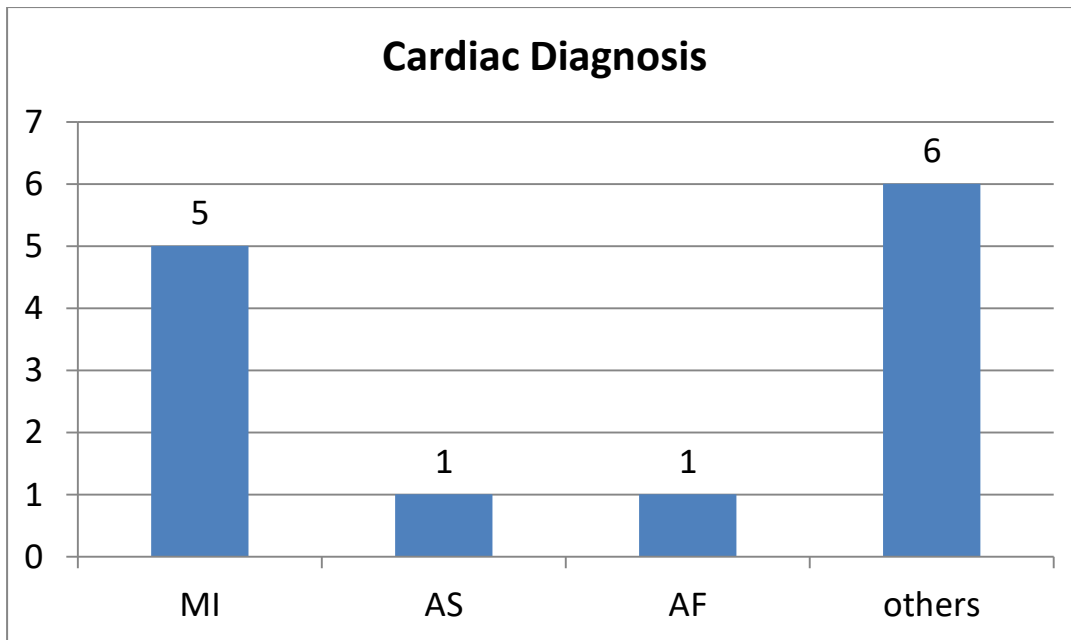


Figure No 8: Cardiac Disease (13)

(MI-MYOCARDIAL INFARCTION, AS-AORTIC STENOSIS, AF-ATRIAL FIBRILLATION)

RCRI (Lee's Revised cardiac risk index):

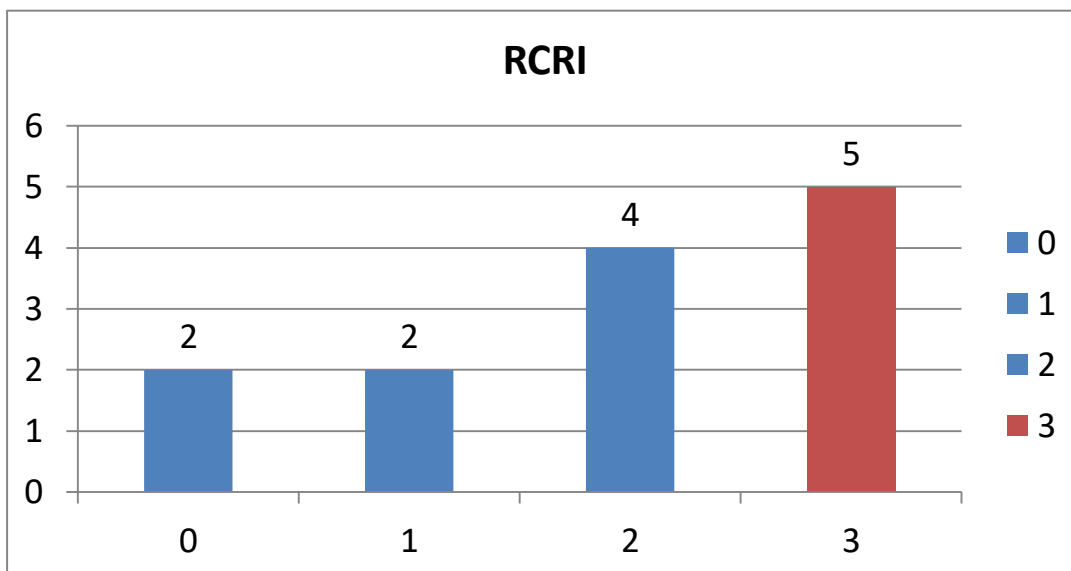


Figure No: 9: RCRI Index

5 patients had Ejection fraction less than 45%.

6. ANAESTHESIA:

All patients underwent one of two types, General anaesthesia and Regional-Spinal with or without Epidural for postoperative analgesia.

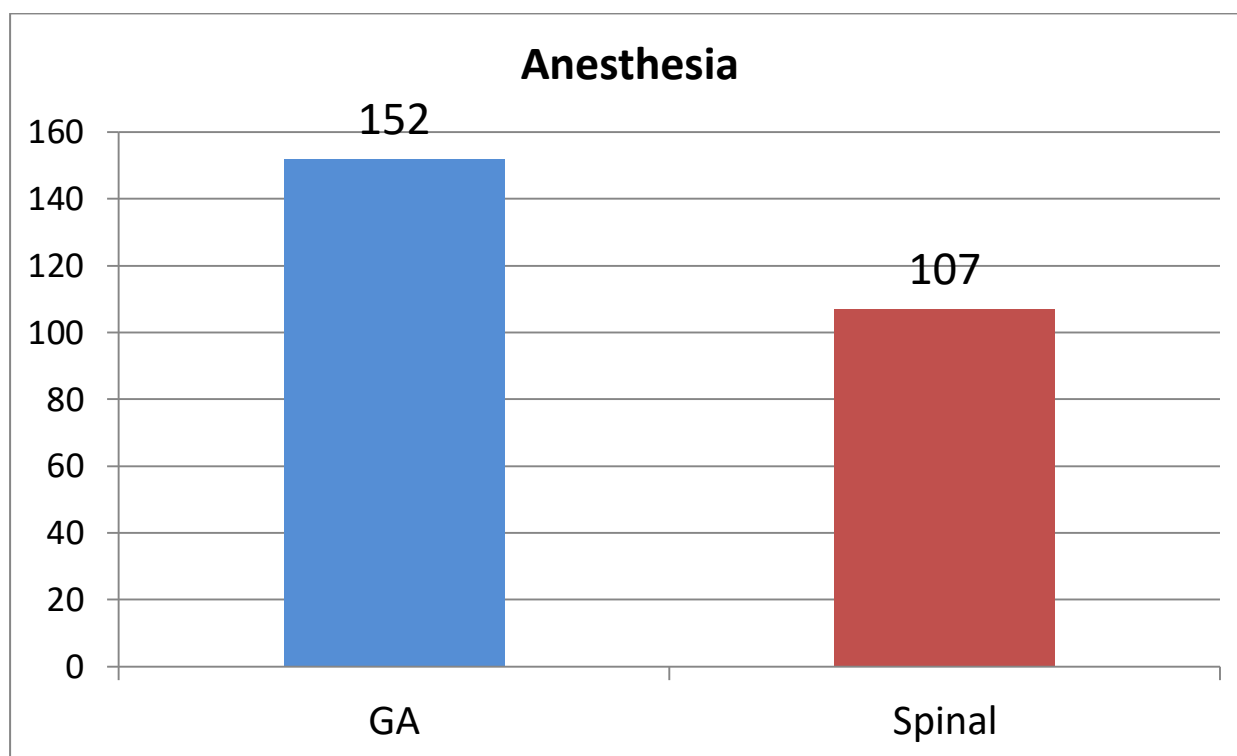


Figure no10: Type of Anaesthesia

Hip:

Out of 117 patients, **94 patients (80%)** received **General anaesthesia**.

Knee:

Out 142 patients, **84 patients had Spinal (60%)**.

7. Body Mass Index(BMI):

The average BMI in our study was **26.3**, Hips: 23.95, Knees: 28.11

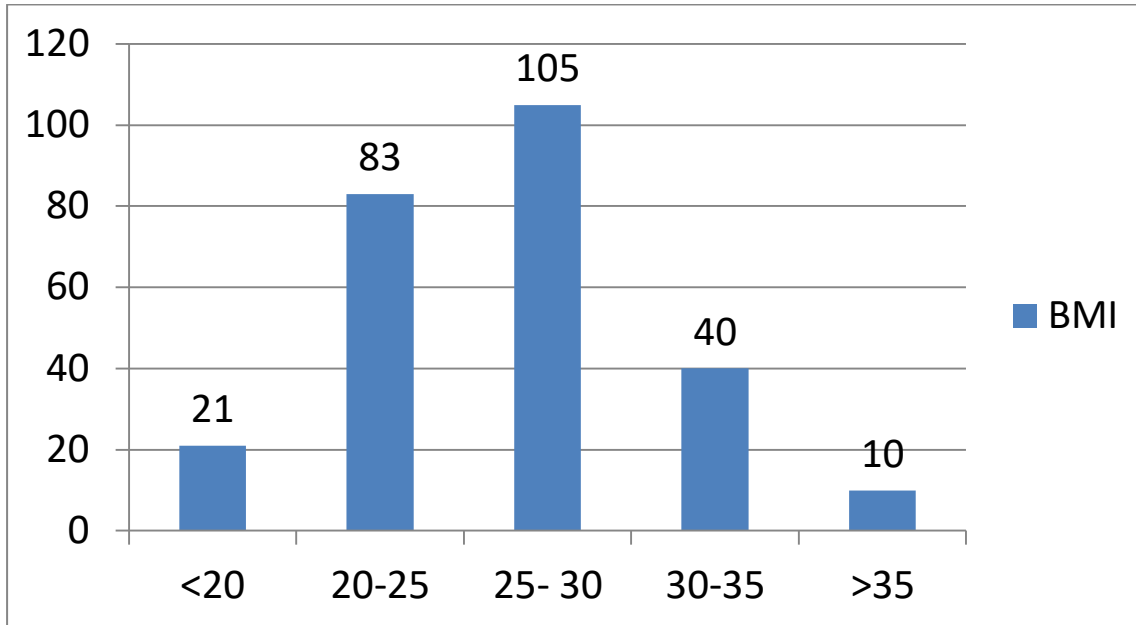


Figure No 11: BMI

8. ASA Grade:

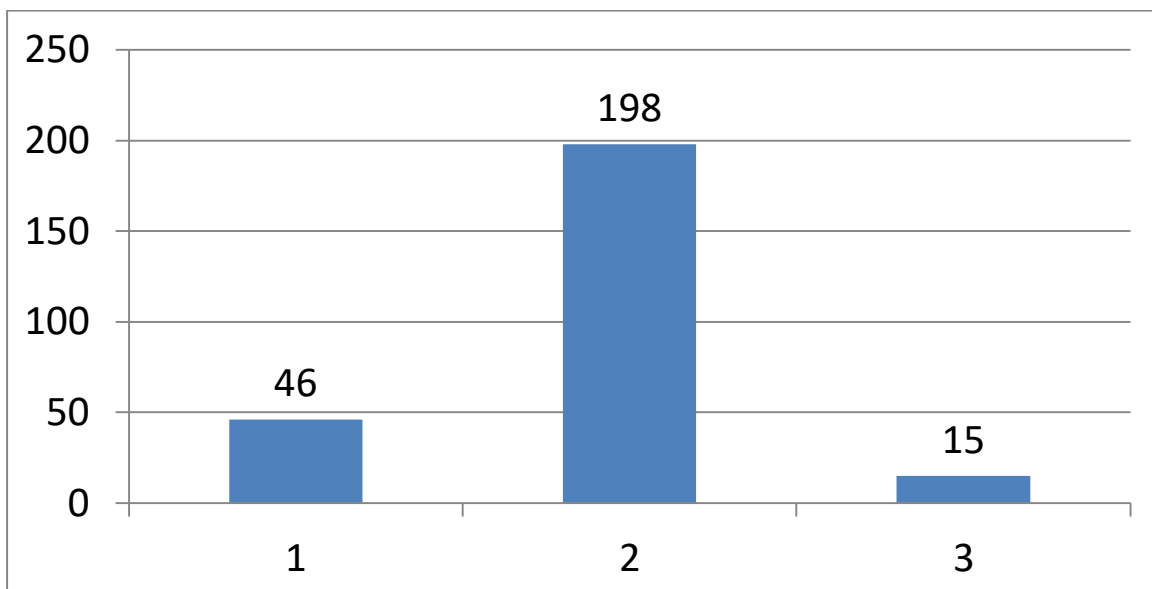


Figure no 12: ASA grade

The American society of Anaesthesiologists graded patient's physical status and fitness of patients before surgery.

We had 15 patients with ASA grade 3, who had uncontrolled medical problems.

9. Duration of surgery:

The average duration of surgery was 176 minutes (100-330minutes)

Average duration for a simultaneous Hip: 183.53 minutes

Average duration for a simultaneous Knee: 169.93 minutes

10. Starting Packed Cell Volume-PCV

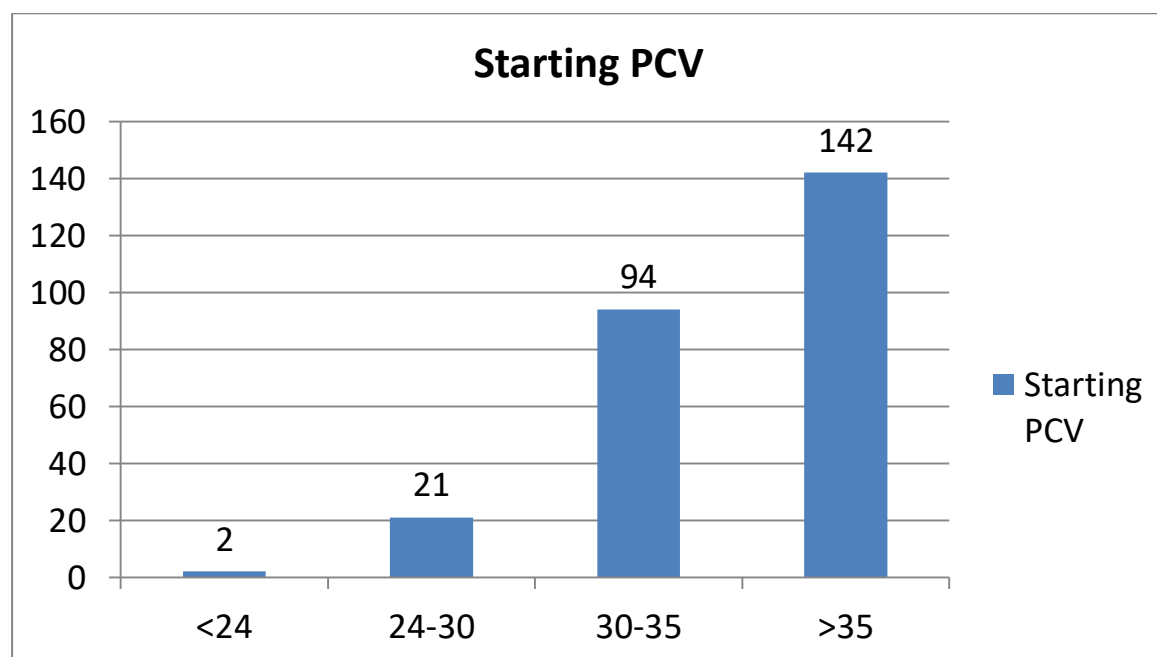


Figure no 13: Starting PCV

The mean starting PCV is -36.48

23 (8.88%) of patients had a starting PCV below the required value of a minimum of 30.

B) COMPLICATIONS

1. BLOOD TRANSFUSION:

Mean Transfusion rate per single stage surgery:

Hip: 1.03units

Knee: 0.35units

Overall: 0.69units

1.1. Intraoperative transfusion:

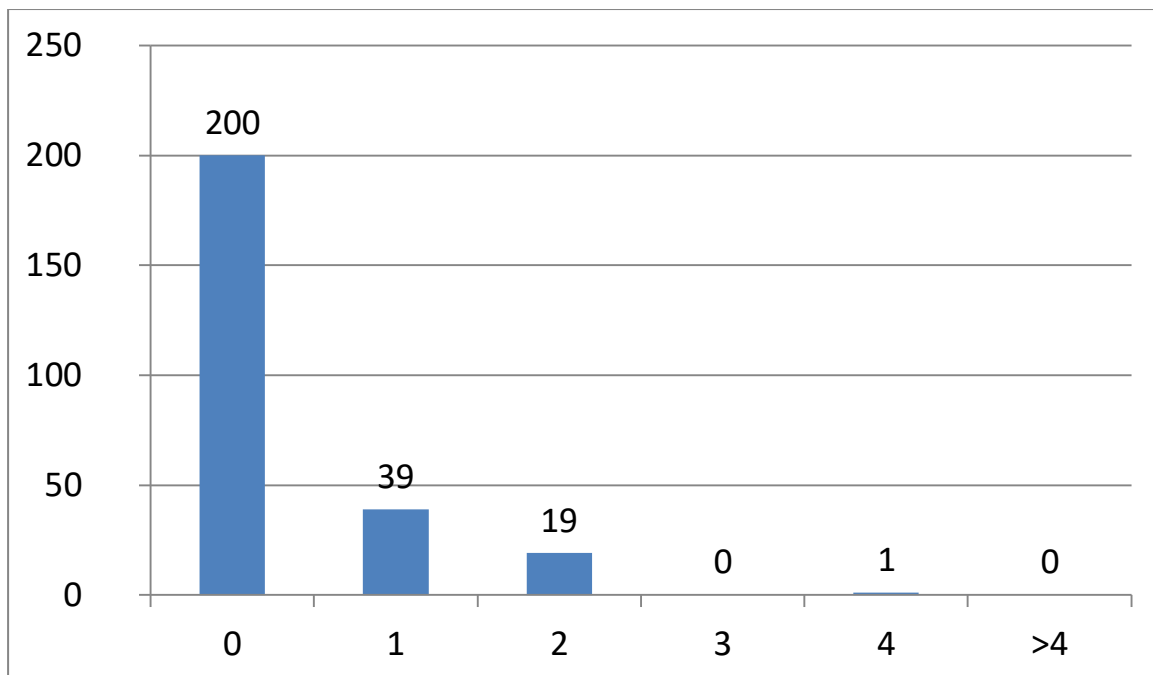


Figure no14: Intra operative transfusions

200(77.2%) patients required no blood transfusions intraoperatively.

19 (7.33%) patients required 2 or more blood transfusions.

1.2. Postoperative transfusion:

Among hips, 14.5 % (17/117) of the patients needed 2 or more transfusions intraoperatively and 12.7 % (15/117) needed 2 or more post operatively.

It was found that among the hips, those who had 2 or more transfusions the mean duration of surgery was 214 min, 30 min more than for patients who received less than 2 transfusions.

Among Knees, 2.11 % (3/142) of the patients needed 2 or more transfusions intraoperatively and 11 % (10/142) of patients needed 2 or more units post operatively.

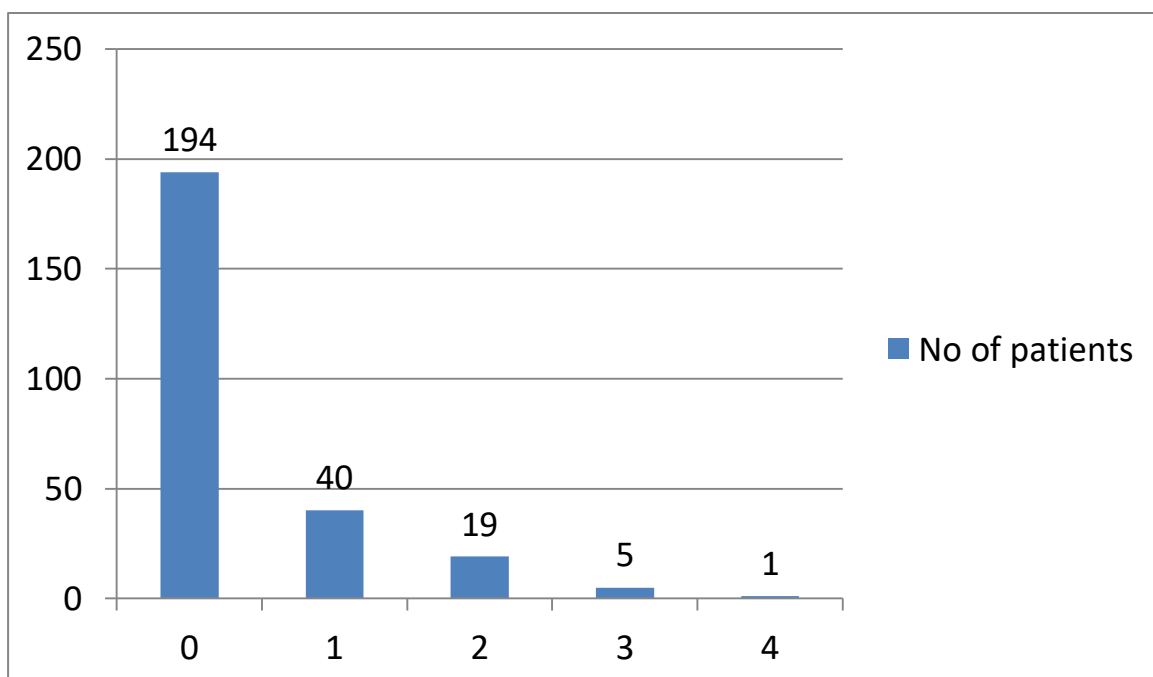


Figure no 15: –Postoperative transfusion

1.3. Total Perioperative transfusion :

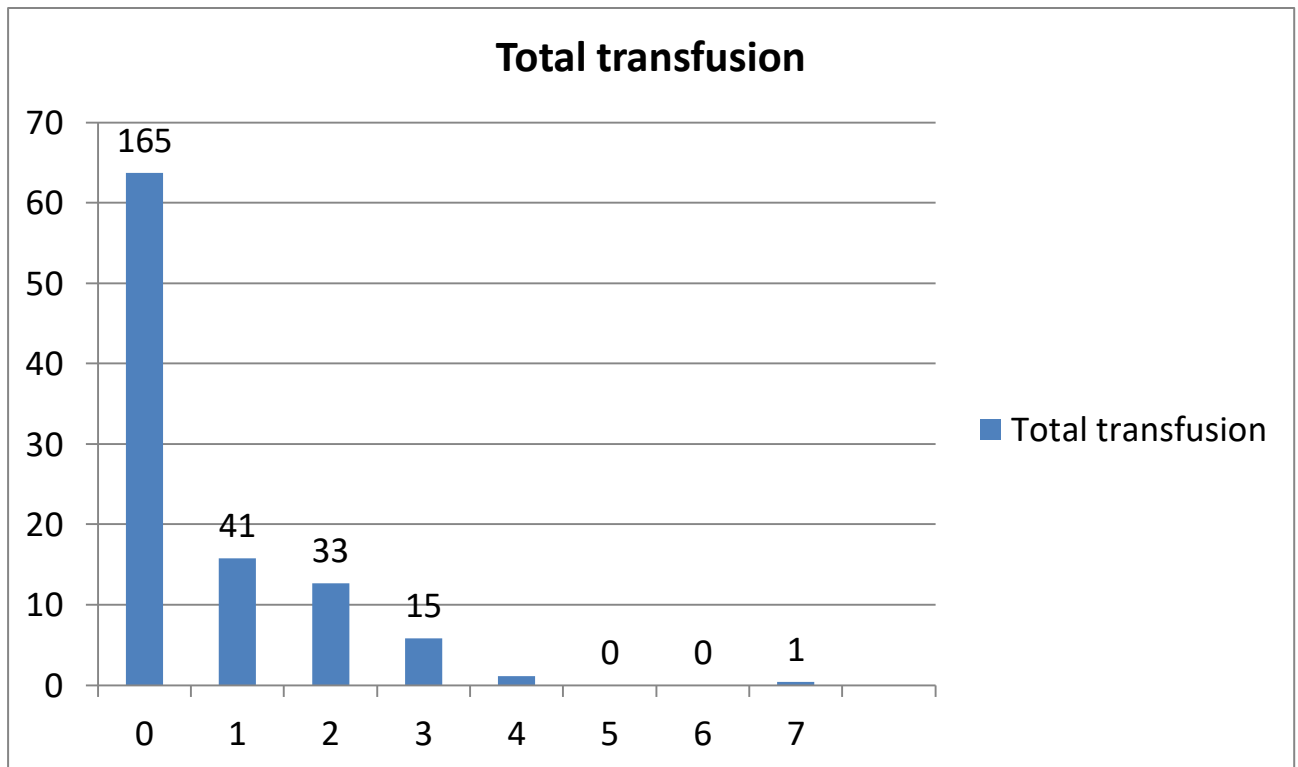


Figure no 16: Total transfusions

63.7% patients did not require any transfusions.

52/259 (20.07 %) had 2 or more transfusions in the peri-operative period.

Among patients who had inflammatory arthritis as diagnosis 33.9 % (38/112)

required two or more peri operative transfusions

HIPS:

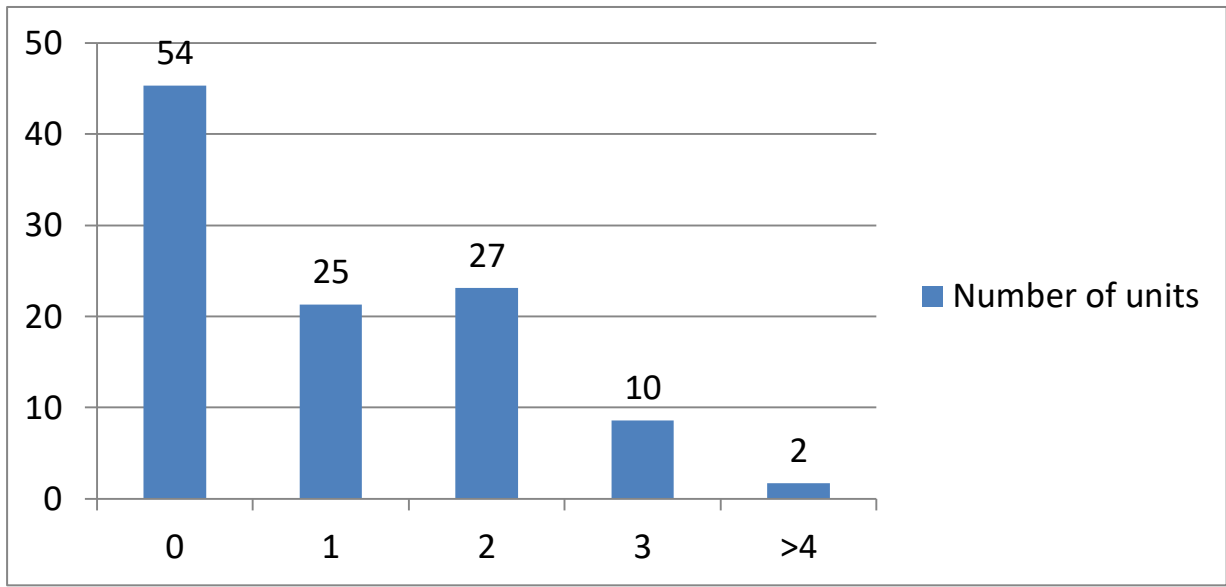


Figure no 17: Total transfusion Hips

KNEE:

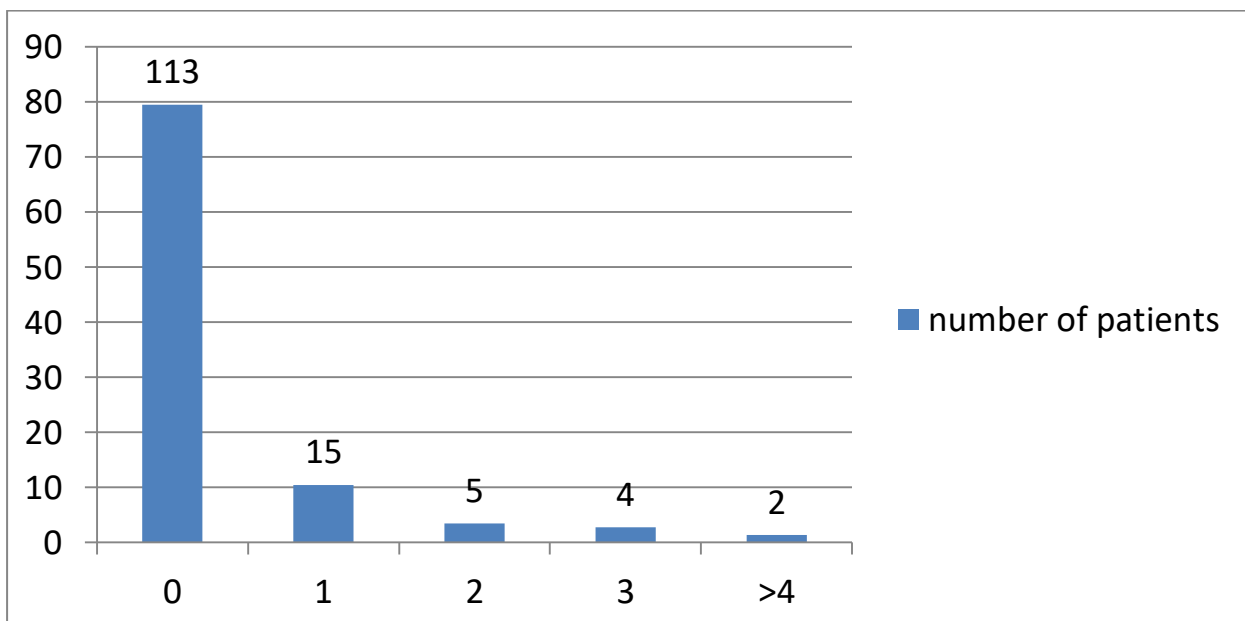


Figure no 18: Total transfusion Knees

80% Patients did not require transfusions among knees.

2. Drop in Haemoglobin:

Mean Drop-2.59g

Mean Drop in Hips-2.98

Mean Drop in Knees-2.26

3. Intraoperative complication:

3.1. Hypotension:

Incidence of Significant hypotension: MAP <50mm Hg for >10min

Overall: 6/259=2.3% Hips: 3/117=2.5% Knees: 3/142=2.11%

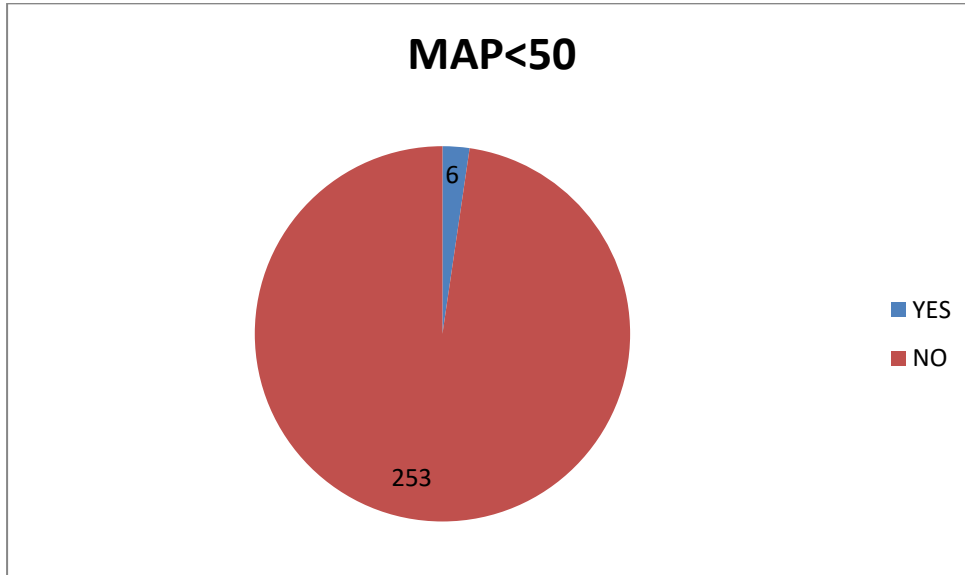


Figure no 19: Intraoperative Hypotension

3.2. Desaturation:

Incidence of desaturation:

Overall: $8/259=3\%$, Hips: $3/117=2.5\%$, Knees: $5/142=3.5\%$



Figure no 20: Desaturation

3.3. Cardiac Arrhythmia:

Incidence of Cardiac arrhythmias:

Overall: $2/259=0.77\%$

Hips: $0/117=0$

Knees: $2/142=1.4\%$

-The 1st patient was a 61 year old gentleman, diabetic and hypertensive with IHD-post surgery and ICD-EF -37%, ASA grade 3, his surgery went on for 205 min. He developed Rhythm disorder with pVcs and had hypotension and was shifted to ICU.

-The 2nd patient was a 37 year old with ankylosing spondylitis no co morbidities who developed st depression and SVT was also shifted to ICU for monitoring and stabilisation.

Total Incidence of intraoperative complications=6.1%

4. Local Complications:

Overall Incidence: $5/259=1.93\%$

Bilateral Hips: $1/117=0.85\%$

Bilateral Knee: $4/142=2.81\%$

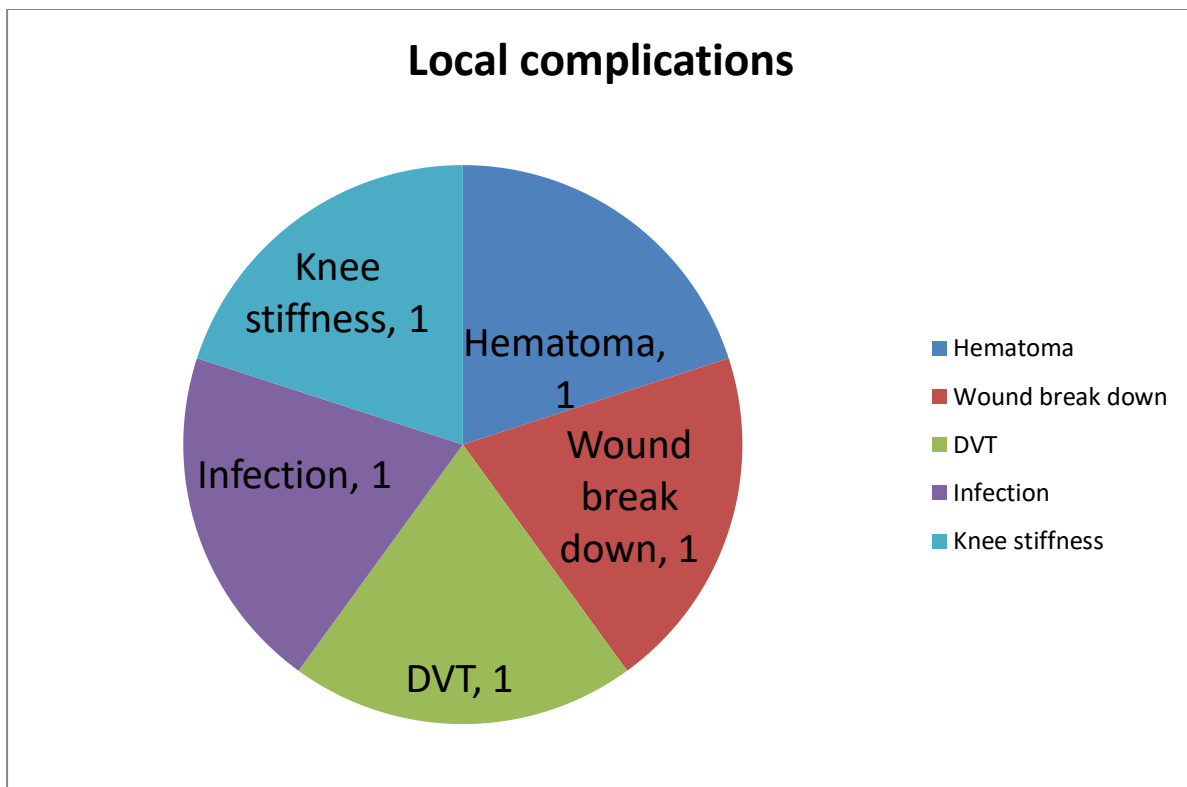


Figure no21: Local Complications

5. Systemic Complications:

Overall: $5/259=1.93\%$

Bilateral hips: $2/117=1.7\%$

Bilateral Knees: $3/142=2.11\%$

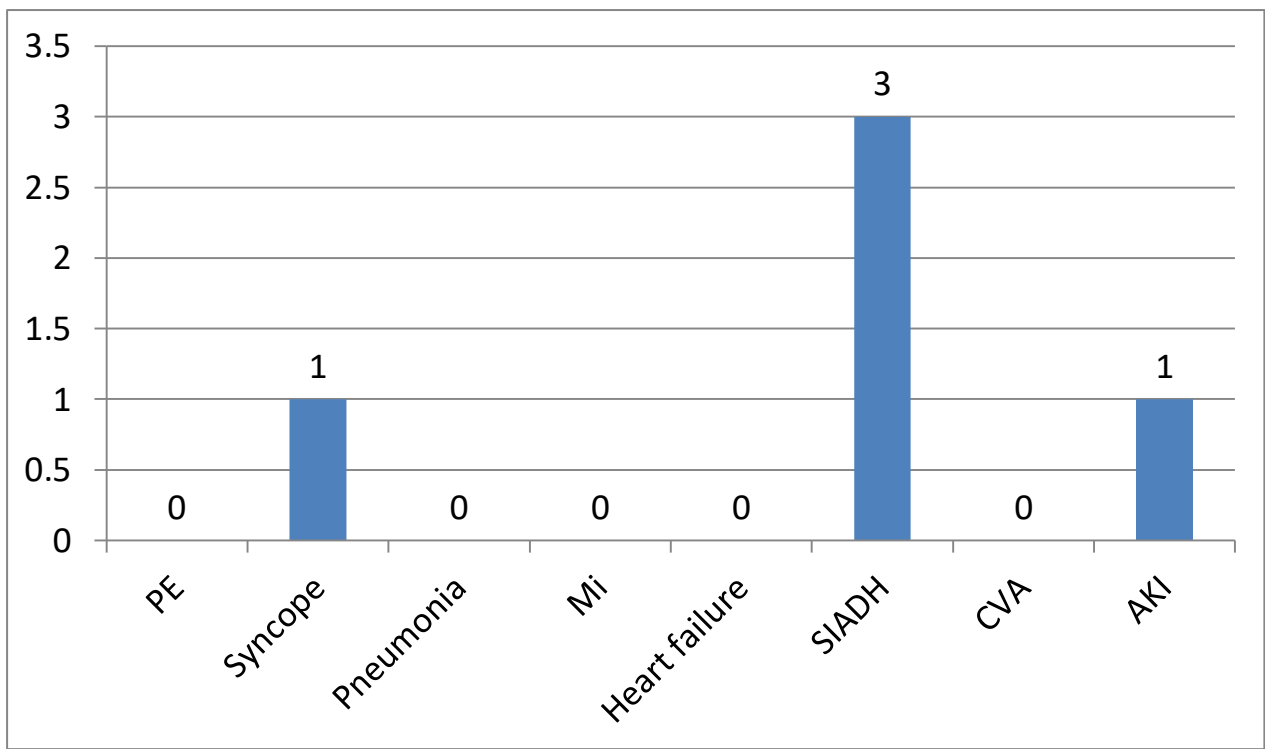


Figure no 22: Systemic complications

5 patients had urinary retention in the post-operative period requiring catheterization.

A medical referral was executed for the above patients and they were medically managed and discharged.

6. ICU Admission:

-Overall Rate of ICU Admission 2013-2019=4.2 %(11/259)

-Bilateral Simultaneous Hips= 5.98 %(7/117)

-Bilateral Simultaneous Knees=2.81 %(4/142)

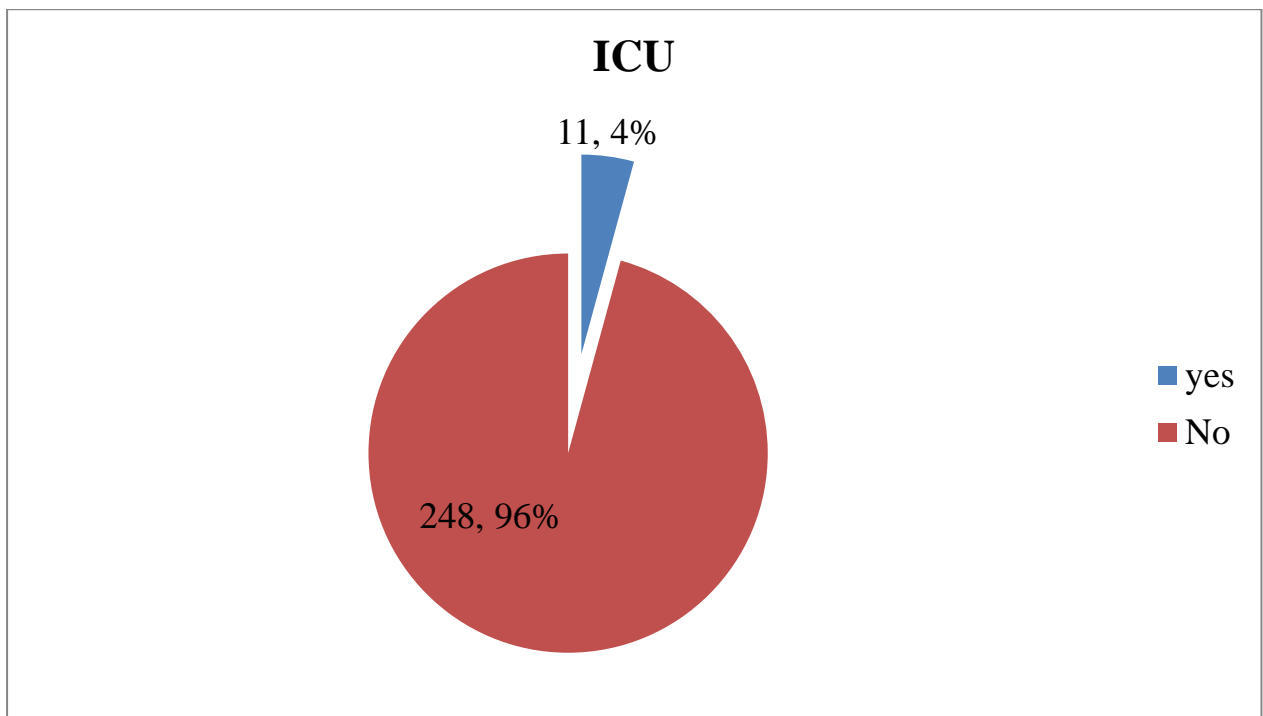


Figure no 23: ICU admissions

Knee:

1 Each for low ventilation, arrhythmia, metabolic and hypotension.

Hip:

Blood loss- 3, Ventilation- 1, Metabolic- 1, Chest pain- 1, Hypotension - 1.

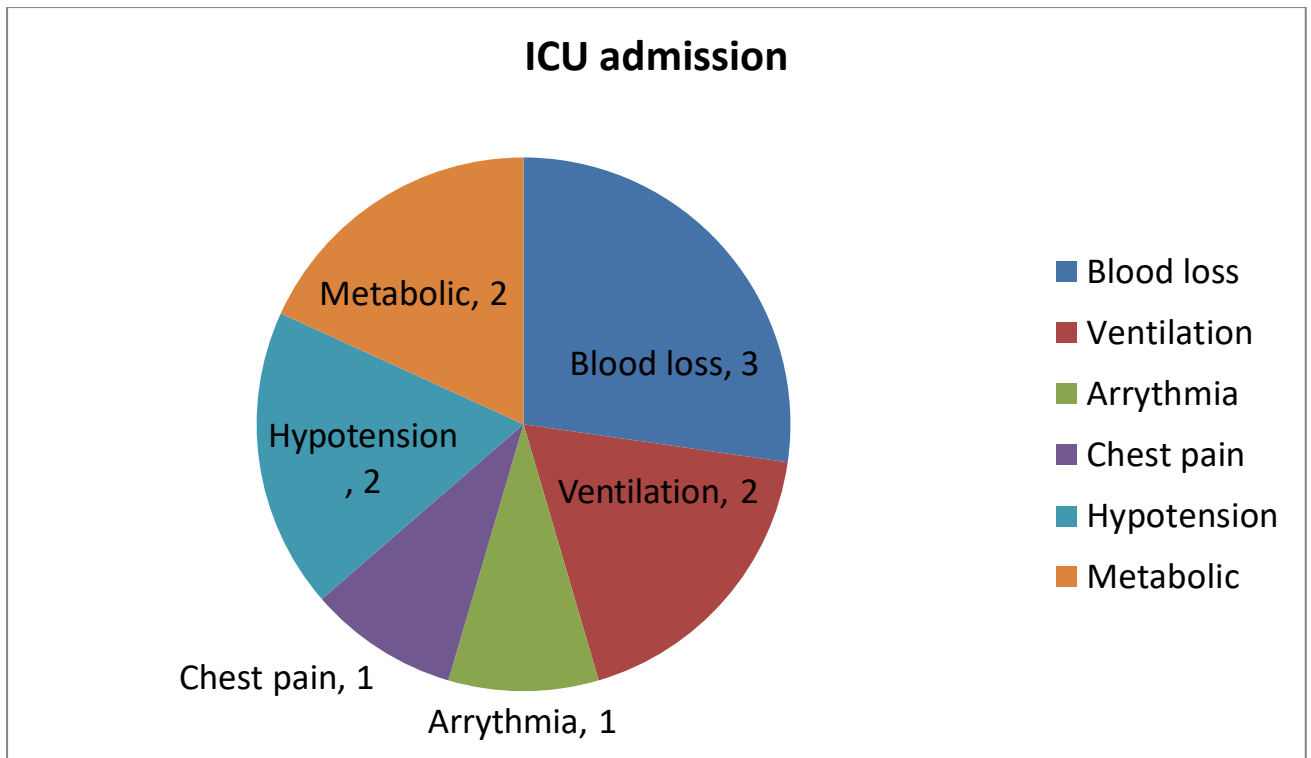


Figure no24: Indications for ICU admission

7. Mortality:

There were no mortalities recorded in our study of 259 patients.

8. Readmission rates

1/259= 0.38%

1 patient was admitted with wound gapping after a fall at his residence after discharge.

Multivariate Analysis for both hips and knees-259 patients

A separate analysis for hips and knees could not be performed as, the number of complications were too low. Hence the whole cohorts of patients in both groups were studied together.

1. Intraoperative complication:

Exposure	Adjusted ODDS ratio(95% CI)	P value
CARDIAC	21.7(6.3 - 74.4)	0.01
ASA >=3	5.2 (1.4 - 19.4)	0.014
STARTING PCV<30	1.9 (.46 - 7.9)	0.37
DURATION>210	0.7 (.13 - 3.9)	0.69
AGE >70	3.2(.74 - 13.6)	0.12
BMI>35	0.72 (.04 - 12.8)	0.82
DIAGNOSIS-INFLAMMATORY	0.49 (.16 - 1.5)	0.21
DIABETES	0.9 (.2 - 3.6)	0.89
CKD	4.5 (.68 - 29.5)	0.12
ASTHMA/COPD	0.6 (.03 - 10.6)	0.73

2. Blood transfusion:

Exposure	Adjusted ODDS ratio(95% CI)	P value
CARDIAC	2.7 (.89 - 8.31)	0.08
ASA >=3	3.8 (1.3 - 10.8)	0.01
STARTING PCV<30	5.2(2.2- 12.5)	0.00
STARTING PCV <36	3.5(1.8-6.7)	0.001
DURATION>210	3.8 (1.7 - 8.3)	0.001
DIAGNOSIS- INFLAMMATORY	4.7(2.4-9.2)	0.001
AGE >70	0.39 (.07 - 2.14)	0.28
BMI>35	1.16 (.27 - 4.9)	0.84
DIABETES	.9 (.40 - 2.1)	0.86
CKD	.29 (.016 - 5.3)	0.40
ASTHMA/COPD	.15 (.008 - 2.5)	0.19

3. Total complications:

Exposure	Adjusted ODDS ratio(95% CI)	P value
CARDIAC	<u>14.9(4.58 - 49.0)</u>	<u>0.0</u>
ASA >=3	<u>3.8(1.07 - 14.0)</u>	<u>0.039</u>
STARTING PCV<30	<u>1.45(.36- 5.8)</u>	<u>0.59</u>

DURATION>210	<u>.53(.097 - 2.9)</u>	<u>0.48</u>
AGE >70	<u>2.4 (.57- 10.1)</u>	<u>0.23</u>
BMI>35	<u>.56(.03 - 9.9)</u>	<u>0.69</u>
DIAGNOSIS- INFLAMMATORY	<u>.6(.23- 1.6)</u>	<u>0.32</u>
DIABETES	<u>.68(.17- 2.6)</u>	<u>0.59</u>
CKD	<u>3.4(.53- 22.4)</u>	<u>0.19</u>
ASTHMA/COPD	<u>.46(.026 - 8.21)</u>	<u>0.60</u>

4. ICU

Exposure	Adjusted ODDS ratio(95% CI)	P value
CARDIAC	<u>.054 (.0010- 2.9)</u>	<u>0.15</u>
ASA >=3	<u>.06 (.001- 3.3)</u>	<u>0.17</u>
STARTING PCV<30	<u>.09 (.001- 5.1)</u>	<u>0.25</u>
DURATION>210	<u>.14(.002- 7.3)</u>	<u>0.33</u>
AGE >70	<u>.06(.001- 3.3)</u>	<u>0.17</u>
BMI>35	<u>.04(.0007- 2.2)</u>	<u>0.12</u>
DIAGNOSIS- INFLAMMATORY	<u>.76(.015- 38.7)</u>	<u>0.89</u>
DIABETES	<u>.2(.004- 10.2)</u>	<u>0.42</u>
CKD	<u>.02(.00048- 1.40)</u>	<u>0.07</u>
ASTHMA/COPD	<u>.050(.0009- 2.6)</u>	<u>0.14</u>

DISCUSSION

Bilateral sequential arthroplasty has been performed from the 1960's. Since then a large number of studies including large meta-analysis have been performed to chalk out its advantages and disadvantages and till now the debate has reached no level ground. In most cases the study is affected by selection bias, differences in confounders between populations, the lack of standardization of outcomes, and ignoring the fact that it is inappropriate to group staged surgeries without subgroups analysis considering the time lapse between staged procedures. However, there has been a steep rise in the number of bilateral sequential surgeries being done, all over the world with inconclusive results in terms of its outcome. In the recent past in India we had experienced a couple deaths following a single stage surgery, which caused uproar from the people and media and as a result of which sequential surgery has faced heavy criticism with severe litigation.

The advantages of having a simultaneous procedure include only one surgical event, single anaesthesia, total anaesthetic duration is less, shorter hospital stay and early rehabilitation of the patient, procedure is cost effective and patient compliance is good. On the other hand it is argued by some authors that there is a higher risk of deep vein thrombosis, cardio pulmonary problems and more need for blood and blood products.

In our setting, sequential surgeries have been performed for the last 15 odd years, and despite the results of an audit conducted in 2010-2012 showing some unfavourable results, over the last 6-7 years, we have been able to standardise protocols by which we have seen excellent results overall.

Our study done between 2013-2019 had 259 patients. The cohort was equally balanced by sex and had a population with a mean age of 47 years (57-knees, 35-hips).

In all, we had 111(42.8%) patients with inflammatory aetiology and 116(44.7%) primary degenerative, very much different from the western scenario who have a larger number of degenerative patients and fewer inflammatory. 45 (17.8%) patients had 2 or more co morbidities, 13 patients having a cardiac disease of whom, 5 were high risk and 5 patients had an ejection fraction of less than 45%. Patients were assessed preoperatively using ASA scoring as a tool, 15 patients were ASA 3.

Duration of surgery was noted from the anaesthesia record and we found that 42 patients had duration of surgery >210min in whom the risks of having blood transfusions increased. We also looked at the starting PCV, 116 patients had a starting PCV<36, we found in them that they had a risk of higher rate of transfusion of 2 or more units of blood.

a) Blood transfusion:

Most studies have shown the requirement for blood and blood products are much higher in sequential or simultaneous surgeries as opposed to staged or unilateral. Problems with increased rate of blood transfusions are increase in infections and immune reactions .However since the era of perioperative tranexamic acid had started it has proven to be effective in bringing down perioperative blood loss. All our

sequential patients received 3 doses of tranexamic acid in the perioperative period unless contraindicated by the anaesthetist.

Author	Surgery	No of patients	Mean Blood units
2019-T.P Sulco et al	Simultaneous Knees	501	2.6
2011-Sabari et al	Simultaneous Knees	30	1.7
2013-Sergio et al	Simultaneous Hips	63	1.5
2005-Stubbs et al	Simultaneous Knees	61	3.59
2010- CMC Study	Sequential Knees+Hips	95	1.4(Hips- 1.9,Knees-1.1)
2019- CMC study(present study)	Sequential Knees+Hips	259	0.69(Hips-1.03, Knees-0.35)

Our study showed a very low requirement of blood units following simultaneous surgeries, one of the lowest published in literature. The reason for this being, good patient selection, pre-operative Hb>10 at least if not 12, standardised anaesthesia

protocols, use of tranexameic acid preoperatively, and accurate surgical and transfusion protocols.

b) Intra-Operative Complications:

Three intraoperative complications were looked at namely, hypotension, desaturation, and cardiac arrhythmia. These were findings from the Anaesthesia record and the anaesthetist's notes.

In literature only a handful of studies have talked about intra-operative complications as such. An article in India by PereddySomashekhara Reddy et al from Apollo hospitals showed that none of his 126 patients had any intraoperative hypotension. In a study by T.P.Sulco in 2017 on bilateral simultaneous knees, found 5% patients with cardiac arrhythmia in the intraoperative and immediate postoperative period.

The reason for the large difference between the studies done in CMC was primarily in the difference in the number of hypotension cases, which could be due to the difference in definition. In the old study, hypotension was defined as systolic blood pressure <90mmHg for >10min or drop of >20mmHg of the average systolic pressures during surgery. However we had defined hypotension as drop in MAP<50mmHg for >10min.

The following were the results of the two studies conducted in our institution:

Study	No of patients	Complications %	Overall intra operative complications %
2010-Cmc study	95	Hypotension-41% Desaturation-2.1% Arrhythmia-2.1%	45.2%
2019-Cmc study(present)	259	Hypotension-2.34% Desaturation-3% Arrhythmia-0.77%	6.11%

c) Local Complications:

In the post-operative period, we looked for the following local complications as defined earlier in our methodology, Hematoma, wound break down, DVT, infection, fracture, dislocation and stiffness.

Most studies showed in single stage or staged surgeries, the rates of wound complications were almost comparable but some authors say bilateral procedure has a higher chance of wound related problems.

Author	Surgery	No of patients	Local complications% (no).
2017 T.P Sulco et al	B/l Knees	501	2.19%(11)
2019-Tan et al	B/l Hips	432	1.38(6)
2015-Sergio et al	B/l Knees	220	4%(9)
2010-CMC study	B/l Knees and Hips	95	9.5%(9)
2019-CMC study	B/lKnees and Hips	259	1.93%(5)

From among recent studies our study done in 2019 showed a very low percentage of complications 1.93%, with one case of DVT and no fractures or dislocations. The low percentage of complications is attributed to the uniform surgical protocol –primary surgeon staying till wound closure and post-operative rehabilitation protocols.

d) Systemic complications:

Systemic complications included: pulmonary embolism, syncope, pneumonia, MI, heart failure, syndrome of inappropriate anti diuretic hormone and acute kidney injury. (Including major and minor complications)

Authors	Surgery	No of patients	Complications %
2015-Sergio et al	Bilateral knees	220	10%
2017-Sulco et al	B/l knees	501	8.4%
2015-Linda et al	B/l Knees	973	5.7%(55)
2010-CMC Study	B/l Knees and Hips	95	25.2%(24)
2019-CMC Study	B/l Knees and Hips	259	1.93%(5)

Our study showed a surprisingly low rate of systemic complications and no major ones like pulmonary embolism, cardiac or neurological events. There was one case of syncope, 3 cases of SIADH and one case of acute kidney injury, all of them recovered with medical therapy within the same admission.

This could be due to the uniform post-operative protocol for transfusion, ambulation and physiotherapy and anti-coagulation.

e) ICU admission:

Admission of patients to Intensive care unit or high dependency unit was based on a decision taken by the Anaesthetist in discussion with the intensivist. No patients in this study were admitted without reason only for overnight monitoring.

The following studies included planned and unplanned ICU admissions also.

Author	Surgery	No of patients	ICU Admission %
2005-Krishna Kiran et al	B /l Knee	50	2%(1)
2005-Geoffery Stubbs et al	B/l knee	61	45.9%
2010 –CMC study	B/l Hips and Knees	95	46.3%(49)
2019-CMC study	B/l Knees and Hips	259	4.2%(11)

11 patients were admitted to the Intensive care unit, the most common reason being blood loss and hypotension. All these patients were stabilised and shifted out to the wards within a day or two without any other problems. The reason for the large discrepancy between our prior study and the current one was that a large number of patients up to 2012 were being shifted to ICU just for post-operative monitoring and not for any specific indication.

f) Readmission Rate

The readmission rate in our study was defined as any patient readmitted with any complications related to the surgery 3 months from the date of surgery.

We had only one patient readmitted following a fall after going home after which he had wound gaping. The total readmission rate in our study was 0.38%.

Linda et al in 2015 showed the readmission rates among 973 patients to be 3.8%.

Mina .W.Morcos et al (53) in 2018 showed that the 30 day readmission rates were 3.5%.

g) Mortality

Though many studies have shown a greater percentage of mortality associated with sequential surgeries as compared with staged or unilateral, in our series of 259 patients we had no mortalities.

Study	Mortality Rate
Sheth et al	0.28%
Chua et al	0.17%
2010 CMC study	1.05%(1)
2019 CMC STUDY	0

Most studies have shown a mortality rate between 0.25-0.30% for sequential/simultaneous surgeries as opposed to 0.15-0.20 for unilateral surgeries.

At the beginning of this study we started off with 2 questions:

1. Is bilateral sequential arthroplasty a safe procedure?

It is evident from the above results from our study that, though perioperative complications do exist as a single stage total joint replacement is a demanding procedure, with good patient selection, change in our systems, stringent and uniform protocols, we were able to bring down our complications to <5% as we expected, with no mortality, no major systemic complications and with an overall transfusion rate of 0.69.

2. What are the perioperative Variables which increase the risk of complications following a single stage bilateral joint replacement surgery?

Our second goal was to identify variables which increase the risks of this procedure, so we performed a multivariate analysis between the risk factors and outcomes.

a) Total Complications:

Patients with a cardiac disease and ASA 3 or higher had a significantly higher risk of total overall complications:

Risk Factor	Pvalue	Adjusted ODDS Ratio
CARDIAC	P<0.001	14.9
ASA>3	P<0.039	3.8

b) Blood Transfusion:

The following were the factors which significantly increased the chance of a patient having two or more peri-operative transfusion.

Risk Factor	P-Value	Adjusted Odds Ratio
ASA>3	0.010	3.87
PCV<30	0.000	5.28
PCV<36	0.001	3.5
Duration >210min	0.001	3.86
Inflammatory conditions	0.000	4.758

As prior studies showed that the cut off for the pre op PCV should be 36,our study also showed that the number of patients having two or more transfusion in the

perioperative period was significant high with PCV <36, but at <30 the Relative risk was significantly greater(5.28 vs. 3.5)

c) Intra –operative Complications:

Risk Factors	P Value	Adjusted Odds Ratio
CARDIAC	0.000	21.67
ASA>3	0.014	5.208

In this study over a 6 year period with 259 patients, including a large number of high risk patients and complex diagnosis, with careful peri-operative planning and simple measures and the above mentioned peri-operative protocol in our institution, we were able to produce excellent results in the overall outcome of this procedure for our patients. With better patient selection we hope to see even better results with the single stage surgery and make it a safe option for patients with indications for the same.

Conclusions

1. Bilateral single stage arthroplasty is a safe option in select patients, with
 - well controlled co morbidities (ASA 1,2)
 - minimal cardiac disease
 - preoperative haemoglobin of at least 36

2. Changes introduced to reduce morbidity associated with bilateral sequential arthroplasty were successful in reducing complications and included
 - 2 senior surgeons operating together ,
 - Main surgeon stays till skin closure
 - Tourniquet release before skin closure
 - Good pain relief programme with pericapsular injections
 - The use of tranexemic acid
 - Stringent postoperative protocols for wound care, anticoagulation and rehabilitation.

3. Patients with ASA grade 3 or > and those with Cardiac disease (Lee criteria >3) had a significantly increased risk of intraoperative complication (Relative risk ASA (5.2) and Cardiac (21.6) and total overall complications. (Relative risks ASA (3.8) and Cardiac (14.9).

4. Patients with Age >70, BMI >35, CKD were not independent risk factors for complications in performing bilateral sequential arthroplasty, but numbers were relatively small.
5. Blood loss with bilateral sequential arthroplasty is not high, with 63.5% of patients having no transfusions following surgery. The transfusion following bilateral knees was 0.35 units of blood/ patient.
6. Factor which increase the likelihood of having two or more units of blood transfusions were:
 - Starting PCV<36(relative risk-3.5)
 - Duration of surgery >210min((as in complex hips and knees)(relative risk-3.8)
 - Arthritis due to inflammatory aetiology- (relative risk-4.7)
 - ASA >3 (relative risk-3.8)
7. 4.2% of patients with bilateral sequential arthroplasty were admitted to the ICU following surgery. The main cause for ICU admission was blood loss and hypotension. No patient was readmitted to the ICU for monitoring.

STRENGTHS OF THE STUDY

1. Large sample size
2. Uniform protocol for all surgeries
3. Same two main surgeons in all cases

LIMITATIONS OF THE STUDY

1. Primarily a retrospective cohort
2. No comparison with staged or unilateral arthroplasty

BIBLIOGRAPHY

1. Skyttä ET, Jarkko L, Antti E, Huhtala H, Ville R. Increasing incidence of hip arthroplasty for primary osteoarthritis in 30- to 59-year-old patients. *Acta Orthop*. 2011 Feb;82(1):1–5.
2. Ibrahim T, Bloch B, Esler CN, Abrams KR, Harper WM. Temporal trends in primary total hip and knee arthroplasty surgery: results from a UK regional joint register, 1991-2004. *Ann R Coll Surg Engl*. 2010 Apr;92(3):231–5.
3. Kumar N, Gupta B, Singh SK. Changing trends of total knee replacement utilization over more than a decade. *Eur J Orthop Surg Traumatol Orthop Traumatol*. 2015 Oct;25(7):1177–80.
4. Memtsoudis SG, Hargett M, Russell LA, Parvizi J, Cats-Baril WL, Stundner O, et al. Consensus statement from the consensus conference on bilateral total knee arthroplasty group. *Clin Orthop*. 2013 Aug;471(8):2649–57.
5. Aghayev E, Beck A, Staub LP, Dietrich D, Melloh M, Orljanski W, et al. Simultaneous bilateral hip replacement reveals superior outcome and fewer complications than two-stage procedures: a prospective study including 1819 patients and 5801 follow-ups from a total joint replacement registry. *BMC Musculoskelet Disord*. 2010;11:1–10.
6. Fu D, Li G, Chen K, Zeng H, Zhang X, Cai Z. Comparison of clinical outcome between simultaneous-bilateral and staged-bilateral total knee arthroplasty: a systematic review of retrospective studies. *J Arthroplasty*. 2013 Aug;28(7):1141–7.
7. Hussain N, Chien T, Hussain F, Bookwala A, Simunovic N, Shetty V, et al. Simultaneous Versus Staged Bilateral Total Knee Arthroplasty. *HSS J*. 2013 Feb;9(1):50–9.
8. Seol JH, Park KS, Yoon TR. Postoperative Complications and Cost-effectiveness of Simultaneous and Staged Bilateral Total Hip Arthroplasty Using a Modified Minimally Invasive Two-incision Technique. *Hip Pelvis*. 2015 Jun;27(2):77–82.
9. Macaulay W, Salvati EA, Sculco TP, Pellicci PM. Single-Stage Bilateral Total Hip Arthroplasty. *JAAOS - J Am Acad Orthop Surg*. 2002 Jun;10(3):217.
10. Leitch KK, Dalgorf D, Borkhoff CM, Kreder HJ. Bilateral total knee arthroplasty — staged or simultaneous? Ontario’s orthopedic surgeons reply. *Can J Surg*. 2005 Aug;48(4):273–6.
11. Walmsley P, Murray A, Brenkel IJ. The practice of bilateral, simultaneous total knee replacement in Scotland over the last decade. Data from the Scottish Arthroplasty Project. *The Knee*. 2006 Mar 1;13(2):102–5.
12. Tsay EL, Grace TR, Vail T, Ward D. Bilateral Simultaneous vs Staged Total Knee Arthroplasty: Minimal Difference in Perioperative Risks. *J Arthroplasty* [Internet]. 2019 Jul 5 [cited 2019 Oct 6]; Available from: <http://www.sciencedirect.com/science/article/pii/S0883540319306564>

13. Ritter M, Mamlin LA, Melfi CA, Katz BP, Freund DA, Arthur DS. Outcome implications for the timing of bilateral total knee arthroplasties. *Clin Orthop*. 1997 Dec;(345):99–105.
14. Reuben JD, Meyers SJ, Cox DD, Elliott M, Watson M, Shim SD. Cost comparison between bilateral simultaneous, staged, and unilateral total joint arthroplasty. *J Arthroplasty*. 1998 Feb;13(2):172–9.
15. Sculco T p. Simultaneous bilateral total knee arthroplasty: does it have a place? *Orthop Proc*. 2017 Aug 1;99-B(SUPP_15):33–33.
16. Restrepo C, Parvizi J, Dietrich T, Einhorn T. Safety of Simultaneous Bilateral Total Knee Arthroplasty A Meta-Analysis. *J Bone Joint Surg Am*. 2007 Jul 1;89:1220–6.
17. Lorenze M, Huo MH, Zatorski LE, Keggi KJ. A Comparison of the Cost Effectiveness of One-Stage Versus Two-Stage Bilateral Total Hip Replacement. *Orthopedics*. 1998 Dec 1;21(12):1249–52.
18. Garland A, Rolfson O, Garellick G, Kärrholm J, Hailer NP. Early postoperative mortality after simultaneous or staged bilateral primary total hip arthroplasty: an observational register study from the swedish Hip arthroplasty register. *BMC Musculoskelet Disord*. 2015 Apr 8;16(1):77.
19. Rasouli MR, Maltenfort MG, Ross D, Hozack WJ, Memtsoudis SG, Parvizi J. Perioperative Morbidity and Mortality Following Bilateral Total Hip Arthroplasty. *J Arthroplasty*. 2014 Jan 1;29(1):142–8.
20. Muskus M, Rojas J, Gutiérrez C, Guio J, Bonilla G, Llinás A. Bilateral Hip Arthroplasty: When Is It Safe to Operate the Second Hip? A Systematic Review [Internet]. *BioMed Research International*. 2018 [cited 2019 Jul 6]. Available from: <https://www.hindawi.com/journals/bmri/2018/3150349/>
21. Cammisa FP, O'Brien SJ, Salvati EA, Sculco TP, Wilson PD, Ranawat CS, et al. One-stage bilateral total hip arthroplasty. A prospective study of perioperative morbidity. *Orthop Clin North Am*. 1988 Jul;19(3):657–68.
22. Reuben JD, Meyers SJ, Cox DD, Elliott M, Watson M, Shim SD. Cost comparison between bilateral simultaneous, staged, and unilateral total joint arthroplasty. *J Arthroplasty*. 1998 Feb 1;13(2):172–9.
23. Saito S, Tokuhashi Y, Ishii T, Mori S, Hosaka K, Taniguchi S. One- Versus Two-stage Bilateral Total Hip Arthroplasty. *Orthopedics* [Internet]. 2010 Aug 1 [cited 2019 Oct 13];33(8). Available from: <https://www.healio.com/orthopedics/journals/ortho/2010-8-33-8/{14a8c121-14f3-435d-9660-93aa090e20f9}/one--versus-two-stage-bilateral-total-hip-arthroplasty>
24. Triantafyllopoulos GK, Memtsoudis SG, Zhang W, Ma Y, Sculco TP, Poultsides LA. Same-Day Surgery Does Not Increase Deep Infection Risk in Bilateral Total Hip Arthroplasty Patients. *J Arthroplasty*. 2016 Sep 1;31(9, Supplement):237–41.
25. C. Babis G, I. Sakellariou V, O. Johnson E, N. Soucacos P. Incidence and Prevention of Thromboembolic Events in One Stage Bilateral Total Hip Arthroplasty: A Systematic Review [Internet]. 2011 [cited 2019 Oct 13]. Available from: <https://www.ingentaconnect.com/content/ben/cvp/2011/00000009/00000001/art00005>

26. Y.-H K, O.-R K, J.-S K. Is one-stage bilateral sequential total hip replacement as safe as unilateral total hip replacement? *J Bone Joint Surg Br* [Internet]. 2009 Mar 1 [cited 2019 Aug 25]; Available from: <https://online.boneandjoint.org.uk/doi/abs/10.1302/0301-620X.91B3.21817>
27. Gromov K, Troelsen A, Stahl Otte K, Ørsnes T, Husted H. Morbidity and mortality after bilateral simultaneous total knee arthroplasty in a fast-track setting. *Acta Orthop*. 2016 Jun;87(3):286–90.
28. Chua HS, Whitehouse SL, Lorimer M, Steiger RD, Guo L, Crawford RW. Mortality and Implant Survival With Simultaneous and Staged Bilateral Total Knee Arthroplasty Experience From the Australian Orthopaedic Association National Joint Replacement Registry. *J Arthroplasty*. 2018 Oct 1;33(10):3167–73.
29. S. Sheth D, Cafri G, W. Paxton E, S Namba R. Bilateral Simultaneous Versus Staged Total Knee Replacement: A Comparison of Complications and Mortality. *J Arthroplasty*. 2016 Mar 1;31.
30. Parvizi J, Pour AE, Peak EL, Sharkey PF, Hozack WJ, Rothman RH. One-stage bilateral total hip arthroplasty compared with unilateral total hip arthroplasty: a prospective study. *J Arthroplasty*. 2006 Sep;21(6 Suppl 2):26–31.
31. Kamath AF, McAuliffe CL, Gutsche JT, Kosseim LM, Hume EL, Baldwin KD, et al. Intensive care monitoring after total joint replacement. *Bone Jt J*. 2013 Nov 1;95-B(11_Supple_A):74–6.
32. Charoencholvanich K, Siri wattanasakul P. Tranexamic Acid Reduces Blood Loss and Blood Transfusion after TKA: A Prospective Randomized Controlled Trial. *Clin Orthop Relat Res*. 2011 Oct 1;469(10):2874–80.
33. Motififard M, Tahririan MA, Saneie M, Badiie S, Nemati A. Low Dose Perioperative Intravenous Tranexamic Acid in Patients Undergoing Total Knee Arthroplasty: A Double-Blind Randomized Placebo Controlled Clinical Trial [Internet]. *Journal of Blood Transfusion*. 2015 [cited 2019 Aug 12]. Available from: <https://www.hindawi.com/journals/jbt/2015/948304/>
34. Nielsen RET, Husted H. [Tranexamic acid reduces blood loss and the need of blood transfusion after knee arthroplasty]. *Ugeskr Laeger*. 2002 Jan 14;164(3):326–9.
35. Burkart BC, Bourne RB, Rorabeck CH, Kirk PG, Nott L. The Efficacy of Tourniquet Release in Blood Conservation After Total Knee Arthroplasty. *Clin Orthop Relat Res 1976-2007*. 1994 Feb;299:147.
36. Rate of Blood Transfusion in Patients Undergoing Bilateral Simultaneous Total Knee Arthroplasty using Patient-Specific Templates and Conventional Techniques: A Comparative Study. 2016;1:6.
37. Newman ET, Watters TS, Lewis JS, Jennings JM, Wellman SS, Attarian DE, et al. Impact of Perioperative Allogeneic and Autologous Blood Transfusion on Acute Wound Infection Following Total Knee and Total Hip Arthroplasty. *J BJS*. 2014 Feb 19;96(4):279.
38. Salvati EA, González ADV, Masri BA, Duncan CP. The infected total hip arthroplasty. *Instr Course Lect*. 2003;52:223–45.
39. Hanssen AD, Rand JA. Evaluation and treatment of infection at the site of a total hip or knee arthroplasty. *J Bone Jt Surg Am Vol Needham*. 1998 Jun;80(6):910.

40. Huotari K, Lyytikäinen O, Seitsalo S. Patient outcomes after simultaneous bilateral total hip and knee joint replacements. *J Hosp Infect.* 2007 Mar 1;65(3):219–25.
41. Hooper GJ, Hooper NM, Rothwell AG, Hobbs T. Bilateral Total Joint Arthroplasty: The Early Results from the New Zealand National Joint Registry. *J Arthroplasty.* 2009 Dec 1;24(8):1174–7.
42. Bozic KJ, Lau E, Kurtz S, Ong K, Rubash H, Vail TP, et al. Patient-Related Risk Factors for Periprosthetic Joint Infection and Postoperative Mortality Following Total Hip Arthroplasty in Medicare Patients. *JBJS.* 2012 May 2;94(9):794.
43. Willis-Owen CA, Konyves A, Martin DK. Factors affecting the incidence of infection in hip and knee replacement. *J Bone Joint Surg Br.* 2010 Aug 1;92-B(8):1128–33.
44. Jenny J-Y, Trojani C, Prudhon J-L, Vielpeau C, Saragaglia D, Houillon C, et al. Simultaneous bilateral total knee arthroplasty. A multicenter feasibility study. *Orthop Traumatol Surg Res.* 2013 Apr 1;99(2):191–5.
45. Rosenbaum AJ, Luciano JA, Marburger R, Hume E. Acute Kidney Injury in the Setting of Knee Arthroplasty: A Case Report and Discussion Investigating Angiotensin-Converting Enzyme Inhibitors as the Culprit. *HSS J.* 2011 Jul;7(2):183–6.
46. Ritter MA, Harty LD, Davis KE, Meding JB, Berend M. Simultaneous bilateral, staged bilateral, and unilateral total knee arthroplasty. A survival analysis. *J Bone Joint Surg Am.* 2003 Aug;85(8):1532–7.
47. Fat embolism during total hip replacement. A prospective study. - PubMed - NCBI [Internet]. [cited 2019 Aug 25]. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/4447670>
48. Yeager AM, Ruel AV, Westrich GH. Are bilateral total joint arthroplasty patients at a higher risk of developing pulmonary embolism following total hip and knee surgery? *J Arthroplasty.* 2014 May;29(5):900–2.
49. Memtsoudis SG, Ma Y, Chiu Y-L, Poultsides L, Gonzalez Della Valle A, Mazumdar M. Bilateral total knee arthroplasty: risk factors for major morbidity and mortality. *Anesth Analg.* 2011 Oct;113(4):784–90.
50. Meehan JP, Danielsen B, Tancredi DJ, Kim S, Jamali AA, White RH. A population-based comparison of the incidence of adverse outcomes after simultaneous-bilateral and staged-bilateral total knee arthroplasty. *J Bone Joint Surg Am.* 2011 Dec 7;93(23):2203–13.
51. Liu L, Liu H, Zhang H, Song J, Zhang L. Bilateral total knee arthroplasty: Simultaneous or staged? A systematic review and meta-analysis. *Medicine (Baltimore).* 2019 May;98(22):e15931.
52. Kiran EK, Malhotra R, Bhan S. Unilateral vs one stage bilateral total knee replacement in rheumatoid and osteoarthritis - A comparative study. *Indian J Orthop.* 2005 Jan 1;39(1):14.
53. Morcos MW, Hart A, Antoniou J, Huk OL, Zukor DJ, Bergeron SG. No Difference in Major Complication and Readmission Rates Following Simultaneous Bilateral vs Unilateral Total Hip Arthroplasty. *J Arthroplasty.* 2018 Aug 1;33(8):2541–5.

ANNEXURES

1. THESIS ABSTRACT

Title: ANALYSIS OF THE PERIOPERATIVE MORBIDITY AND MORTALITY ASSOCIATED WITH BILATERAL SEQUENTIAL TOTAL HIP OR KNEE ARTHROPLASTY.

Department: Orthopaedic surgery

Name of Candidate: Dr. Andrew Isaac Christudoss

Degree: M.S Orthopaedic Surgery

Name of Guide: Prof.Pradeep Mathew Poonnoose

OBJECTIVES:

To study the perioperative morbidity and mortality associated with sequential bilateral arthroplasties of the hip and knee.

METHODS:

All patients who underwent a bilateral sequential arthroplasty from 1.8.2013 to 15.7.2019 were included in the study.

Retrospective Data was collected from hospital records clinical workstation, and blood bank records. Outcomes measured included intra operative complications, local complications and systemic complications, perioperative transfusion rate, drop in haemoglobin, readmission rates, and mortality.

Chi-square test was used to compare the complication rates with categorical variables. Logistic regression analysis was performed to study the relationship between complications and risk factors.

Results:

The overall rate of intraoperative complications was-6%, with 2.3% having Hypotension (MAP<50mm Hg for >10minutes), 3% having drop in saturation (SPO2<90%, and 0.77% having arrhythmias.

The local perioperative complication rate was 1.93% and included (hematoma-1, dvt-1, infection-1, wound break down-1 and knee stiffness-1). None of the patients had major systemic complications like myocardial infarction, pulmonary embolism or cerebrovascular accident, 1.93% had minor systemic complications like (syncope-1, Siadh-3, Aki -1).

80% of the bilateral knees did not require blood transfusion. But 33% of the hips required more than 2 units of blood. The mean drop in Haemoglobin for hips was 2.98% and for knees was 2.26%.

Post-operative ICU admissions was4.2%. There were no mortalities and the readmission rate was0.38%.

Patients with ASA grade ≥ 3 and left cardiac index >3 had a significantly higher chance of intraoperative complications (RR 5.2 and 21.6) and the risk of ICU admissions were also more among these patients.

The likelihood of having 2 or more blood transfusions was more in patients with , Starting pcv <36 (RR-3.5), duration of surgery >3.5 hours(RR-3.8), inflammatory arthritis (RR-4.7), ASA ≥ 3 (RR-3.5).

Conclusions:

Bilateral single stage arthroplasty is a safe option in select patients, with well controlled co morbidities (ASA 1, 2), minimal cardiac disease and preoperative haemoglobin of at least 36.

2. Study Performa

EARLY MORBIDITY& MORTALITY FOLLOWING BILATERAL SEQUENTIAL HIP OR KNEE ARTHROPLASTY

1. Joint involved:
 - a. Hip
 - b. Knee
2. Arthroplasty :
 - a. Unilateral
 - b. Sequential bilateral
If sequential- date of second surgery-
 - c. Simultaneous bilateral
3. Type of prosthesis (for THR):
 - a. Cemented
 - b. Uncemented
 - c. Hybrid

DEMOGRAPHICS

1. Name of the patient:
2. Hospital number:
3. Sex:
 - a. Male
 - b. Female
4. Age at surgery:
 - a. First surgery:
 - b. Second surgery:
5. Date of Surgery:
 - a. First surgery:
 - b. Second surgery:
6. Time (in months) between 2 surgeries:
7. Diagnosis:

<u>HIP</u>	<u>KNEE</u>
Primary osteoarthritis	Primary osteoarthritis
Ankylosing Spondylitis	Ankylosing Spondylitis
Rheumatoid Arthritis	Rheumatoid Arthritis
Other inflammatory Arthritis	Other inflammatory Arthritis
AVN	Post traumatic arthritis

Post traumatic arthritis	Others (Mention)
Dysplastic hip	
Others (Mention)	

8. Co-morbidities:

- a. Nil
- b. DM
- c. HTN
- d. COPD/Asthma
- e. CKD
- f. Others (mention):

9. Body Mass Index (absolute value) : _____ Kg/m²

- a. <20Kg/m²
- b. 20-<25
- c. 25-<30
- d. 30-<35
- e. >/=35

10. ASA grade:

- a. I
- b. II
- c. III
- d. IV

SURGERY DETAILS

1. Anaesthesia:

- a. General Anaesthesia:
- b. Spinal Anaesthesia:

2. Epidural Analgesia:

- a. Yes
- b. No

3. Periarticular cocktail injection:

- a. Yes
- b. No

4. Duration of surgery: (in minutes)

5. Transfusions (Intra/ Post op):

- a. Blood: _____ Units
- b. Products: _____ Units (Mention)

6. DVT prophylaxis:
 - a. Nil
 - b. Mechanical
 - c. Pharmacological
7. Blood loss:
 - a. Drop in Haemoglobin:
 - b. (OR) Drop in PCV:

COMPLICATIONS:

1. Intraoperative complications:

- a. Hypotension(systolic b.p.<90 and or diastolic b.p.<60)
- b. Drop in saturation
- c. Arrhythmias

2. Local complications:

- a. Haematoma
- b. Wound breakdown
- c. Infection
- d. Periprosthetic fracture
- e. Dislocation
- f. Others (Mention)

3. Systemic complications:

- g. Pulmonary Embolism
- h. Syncope / collapse postoperative
- i. Pneumonia
- j. Acute myocardial infarction
- k. Paralytic ileus
- l. Urinary retention requiring catheterisation
- m. CNS infarction
- n. Intra operative hypotension
- o. DVT
- p. Others (Mention)

2. ICU admission:
 - a. Yes
 - b. No
3. If yes: Duration of ICU admission:
4. If yes; Reason for ICU admission:
5. Mortality
 - a. Yes (mention cause)
 - b. No

3. Institution review Board Certificate-



OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., D.V. Med (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pullmoed, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., D.M.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

October 17, 2017

Dr. Andrew Isaac Christudoss,
PG Registrar,
Department of Orthopaedics,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Perioperative morbidity associated with bilateral simultaneous total hip or knee
arthroplasty.
Dr. Andrew Isaac Christudoss, Employment Number: 29633 Post Graduate Registrar,
Department of Orthopaedics Dr. Pradeep. M. Poonnoose, Employment Number: 13033,
Orthopaedics – Unit II, : DR. Anil Thomas Gummien Employment Number: 31288,
Orthopaedics, DR. Jerry George, Employment Number: 29351, Orthopaedics.

Ref: IRB Min. No. 10785 [OBSERVE] dated 01.08.2017


Dear Dr. Andrew Isaac Christudoss,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal
(Research), so that the grant money can be released.

With best wishes,


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
M.B.B.S., MD., D.M.
SECRETARY (ETHICS COMMITTEE)
INSTITUTIONAL REVIEW BOARD
Christian Medical College, Vellore

Cc: Dr. Pradeep. M. Poonnoose, Dept. of Orthopaedics, CMC, Vellore

1 of 4



OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., D. Wa (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pallmoed, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

October 17, 2017

Dr. Andrew Isaac Christudoss,
PG Registrar,
Department of Orthopaedics,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**

Perioperative morbidity associated with bilateral simultaneous total hip or knee arthroplasty.

Dr. Andrew Isaac Christudoss, Employment Number: 29633 Post Graduate Registrar,
Department of Orthopaedics Dr. Pradeep. M. Poonnoose, Employment Number: 13033,
Orthopaedics – Unit II, ; DR. Anil Thomas Oommen Employment Number: 31288,
Orthopaedics, DR. Jerry George, Employment Number: 29351, Orthopaedics.

Ref: IRB Min. No. 10785 [OBSERVE] dated 01.08.2017

Dear Dr. Andrew Isaac Christudoss,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Perioperative morbidity associated with bilateral simultaneous total hip or knee arthroplasty" on August 01st 2017.

The Committee reviewed the following documents:

1. IRB Application Format
2. Proforma for data collection.
3. Cvs of Drs. Andrew Isaac Christudoss, Pradeep. M. Poonnoose, Anil Thomas Oommen, Jerry George
4. No. of documents 1 - 3.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on August 01st 2017 in the Jacob Chandy Hall, Paul Brand Building, Christian Medical College, Vellore 632 004.



**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

Dr. B.J. Prashantham, M.A., M.A., D. Min (Theology)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pullimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA (Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB, Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Jayaprakash Muliylil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist
Dr. RekhaPai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Mr. C. Sampath	BSc, BL.	Advocate, Vellore	External, Legal Expert
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Dr. SachaVarkki	MBBS, DCH, DNB	Professor, Paediatrics, CMC, Vellore	Internal, Clinician
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician



**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

Dr. B.J. Prashantham, M.A., M.A., D. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pullmoos, M.D.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.D.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. AjithSivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Mathew Joseph	MBBS, MCh	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. Shyam Kumar NK	MBBS, DMRD, DNB, FRCR, FRANZCR	Professor, Radiology, CMC, Vellore	Internal, Clinician
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro)Dip, NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Perioperative morbidity associated with bilateral simultaneous total hip or knee arthroplasty" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Final Grant Allocation:

A sum of Rs. 15,000/- INR (Rupees One Lakh Only) will be granted for 2 years.

Yours sincerely,


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
M.D.B.S., MD., DM.
SECRETARY - ETHICS COMMITTEE
Institutional Review Board,
Christian Medical College, Vellore - 690017