INCIDENCE OF ANTERIOR KNEE PAIN POST TOTAL KNEE ARTHROPLASTY IN CORRELATION WITH BODY MASS INDEX

DR GANESHA DEVAN KANAGARAJAH

Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree of Master of Medicine

(ORTHOPAEDICS)

UNIVERSITI SAINS MALAYSIA

2022

INCIDENCE OF ANTERIOR KNEE PAIN POST TOTAL KNEE ARTHROPLASTY IN CORRELATION WITH BODY MASS INDEX

FROM JANUARY 2018 TO JUNE 2020

STUDY VENUE:

HOSPITAL UNIVERSITY SAINS MALAYSIA

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

List of abbreviations:

   i.   AKP refers to anterior knee pain

   ii.   BMI refers to body mass index

   iii.   WHO refers to World Health Organization

   iv.   TKA refers to total knee arthroplasty

   v.   HUSM refers to Hospital Universiti Sains Malaysia

ABSTRACT

Introduction

Anterior knee pain (AKP) post total knee arthroplasty (TKA) is believed to be multifactorial in aetiology with reported incidence of up to 40%. Body mass index (BMI) as a contributing factor to this complication has given mixed results based on previous studies. Given the increasing number of TKA cases done annually and in line with the rising number of overweight and obese populations in Malaysia, we would like to determine if there is a correlation between these two factors.

Methodology

A retrospective cohort study was done to analyse the 78 primary knee arthroplasties without patella resurfacing done in Hospital Universiti Sains Malaysia (HUSM) from 2018 to 2020. Incidence of AKP up to one year post arthroplasty and its correlation with BMI groups and other potential variables were analysed for any significant correlation. Statistical analysis was done using IBM SPSS Statistics Version 25.

Results

There were 22 male and 49 female patients with a mean age of 65.4 years. The incidence of AKP in this study was 5.1% which is relatively lower than average compared to other studies. The mean BMI was 29.6kg/m2 and patients were divided into two groups, first group with normal BMI and second group with overweight & obese BMI. There was no significant correlation between the two BMI groups and incidence of anterior knee pain, however all four patients with AKP were in the overweight group and female.

Conclusion

Anterior knee pain remains a challenging complication post total knee replacement with many factors (patient, implant, surgical techniques) still being heavily debated and studies continue to show mixed results. Although no correlation was found, we strongly recommend our patients to optimize BMI before surgery to reduce the risk of complications as 5.1% of patients with anterior knee pain were all in the overweight group. This is also to reduce other complications which are better established and to better optimize their comorbidities as well as general health prior to arthroplasty. Given the multifactorial cause of AKP, early identification and thorough assessment on a case-to-case basis is recommended to direct individualized patient management until a clear guideline on its prevention & management is established.

Key Words:

Anterior Knee Pain, Total Knee Arthroplasty, Body Mass Index

ABSTRAK

Pengenalan

Sakit lutut anterior yang merupakan komplikasi selepas pembedahan pertukaran sendi lutut boleh disebabkan oleh pelbagai faktor dengan kejadian sampai 40%. Index jisim tubuh sebagai faktor penyebab komplikasi ini masih tidak dapat ditentukan dengan kukuh berdasarkan kajian sedia ada. Dengan peningkatan kes pembedahan penukaran sendi lutut selaras dengan peningkatan jumlah populasi yang berlebihan berat badan dan juga obes di Malaysia, kami hendak mengkaji korelasi antara faktor ini dengan sakit lutut anterior.

Kaedah Kajian

Kajian retrospektif dilakukan untuk menganalisa 78 lutut yang menjalani pembedahan penukaran sendi tanpa penukaran patella di Hospital Universiti Sains Malaysia (HUSM) dari tahun 2018 sehingga 2020. Komplikasi sakit lutut anterior ini disusuli sampai setahun setelah pembedahan dan korelasi dengan golongan index jisim tubuh dan pembolehubah lain dianalisis menggunakan peranti IBM SPSS Statistics Version 25.

Keputusan

Terdapat 22 lelaki dan 49 wanita dalam kajian ini dengan purata umur 65.4 tahun. Kejadian sakit lutut anterior adalah 5.1% iaitu agak rendah bila dibandingkan dengan kajian sedia ada yang lain. Purata indeks jisim tubuh adalah 29.6kg/m2 dan pesakit dibahagikan kepada dua kumpulan iaitu kumpulan pertama dengan index berat ideal dan kumpulan kedua yang berlebihan berat & obes. Tiada korelasi yang ketara antara kumpulan-kumpulan indeks jisim tubuh yang dikaji dengan sakit lutut anterior setelah pembedahan, namun kesemua empat lutut yang mengalami sakit lutut anterior merupakan dalam kumpulan berat berlebihan dan merupakan wanita.

Kesimpulan

Sakit lutut anterior merupakan komplikasi yang mencabar setelah pembedahan penukaran sendi lutut dengan pelbagai faktor (pesakit, implan, teknik pembedahan) yang masih dalam kajian tanpa keputusan yang sehaluan. Walaupun tiada korelasi yang ketara antara kumpulan indeks jisim tubuh dan sakit lutut anterior, kami merekomendasikan semua pesakit untuk mencapai indeks jisim tubuh ideal untuk mengurangkan risiko komplikasi memandangkan 5.1% pesakit yang mendapat sakit lutut anterior semua dalam kategori berat badan berlebihan. Selain itu indeks jisim tubuh ideal mengurangkan komplikasi lain yang sudah diketahui, mengoptimumkan penyakit sedia ada dan memberi kesan kesihatan yang lebih baik. Disebabkan pelbagai faktor boleh menyumbang pada sakit lutut anterior, pengesanan awal dan pemeriksaan menyeluruh hendak dilakukan pada setiap kes untuk membimbing perawatan secara tersendiri untuk setiap pesakit sampai ada garis panduan yang jelas untuk menghindari & merawat komplikasi ini.

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

Total knee arthroplasty is becoming a more frequent procedure done both worldwide and in Malaysia in line with increasing numbers of the elderly population. Anterior knee pain (AKP) post total knee arthroplasty is a common complication which can be attributed to a multifactorial cause, making it challenge to treat (1) . One paper mentioned that almost half of patients complain of anterior knee pain post total knee arthroplasty leading to patient dissatisfaction after surgery and reduced quality of life (2). Current studies are focusing on patella-femoral complications such as increased loading at the joint as a major source of AKP in patients post total knee arthroplasty. Normal kinematic studies have showed increased patella-femoral loading in overweight and obese patients in the native knee with also reports of higher complications post total knee arthroplasty in the higher BMI group (3). Knowing that there is an increasing percentage of overweight and obese people in Malaysia together with increasing numbers of knee arthroplasty being done, we would like to see if there is a correlation between Body Mass Index and Anterior Knee Pain after Total Knee Arthroplasty in the Malaysian population.

1.2 OBJECTIVE

1. To identify incidence of anterior knee pain post total knee arthroplasty at Hospital Universiti Sains Malaysia.

2. To determine association between BMI and incidence of anterior knee pain in patients post total knee arthroplasty.

CHAPTER 2: STUDY PROTOCOL

DISSERTATION PROPOSAL

TITLE: INCIDENCE OF ANTERIOR KNEE PAIN POST TOTAL KNEE ARTHROPLASTY IN CORRELATION WITH BMI

NAME: DR GANESHA DEVAN KANAGARAJAH

MATRIK NO: P-UM0118/19

MMC No: 69624

SUPERVISOR:

PROF DR AMRAN AHMED SHOKRI

2.1 INTRODUCTION

Total knee arthroplasty is becoming a more frequent procedure done both worldwide and in Malaysia in line with increasing numbers of the elderly population. Anterior knee pain post total knee arthroplasty is a common complication which can be attributed to a multifactorial cause, making it a challenge to treat (1). Some reports mention almost half of patients complain of anterior knee pain post total knee arthroplasty leading to patient dissatisfaction after surgery and reduced quality of life (2). Current studies are focusing on patella-femoral complications such as increased loading at the joint as a major source of AKP in patients post total knee arthroplasty. Normal kinematic studies have showed increased patella-femoral loading in overweight and obese patients in the native knee with also reports of higher complications post total knee arthroplasty in the higher BMI group (3). Knowing that there is an increasing percentage of overweight and obese people in Malaysia together with increasing numbers of knee arthroplasty being done, we would like to see if there is a correlation between Body Mass Index and Anterior Knee Pain after Total Knee Arthroplasty in the Malaysian population.

2.2 RATIONALE OF STUDY

To compare the incidence of anterior knee pain post total knee arthroplasty at our centre with those reported at other centres as a measure of standard and quality. To establish a correlation between BMI and anterior knee pain post total knee arthroplasty which may be significant to guide future management and further research.

2.3 LITERATURE REVIEW

2.3.1 ANTERIOR KNEE PAIN POST TOTAL KNEE ARTHROPLASTY

The aim of joint replacement surgery is to restore, as close as possible, a normal functioning, mobile and pain free joint. Anterior knee pain post total knee arthroplasty has been an interesting topic of discussion with a multi factorial cause making it a challenge to treat. Identifying the sole cause may be difficult, thus focus of research is to establish significant correlations of common factors which may be associated with this bothersome complication. Anatomically the anterior part of the knee refers to the patellofemoral joint which consists of different tissue which include bone, synovium, capsule, retinaculum, tendons and the fat pad beneath it (4). Any of these structures in the patellofemoral joint may be the cause of pain or it may be a combination of these structures. The symptoms of AKP after total knee arthroplasty can be described as retro-patellar or peripatellar pain limiting patients in their activities of daily living and quality of life. Patients usually complain of pain at the anterior aspect of the knee and also around or behind the patella.

The definition of anterior knee pain (AKP) encompasses pain experienced in the area of the anterior knee and is usually recognized as a syndrome and a unified consensus in the definition is still lacking (5). Numerous classification systems for AKP have been developed with some based on the tissue specific disorders such as bone, cartilage or soft tissue involvement; whilst several authors also include the cause in their classifications (6). Other classification methods relate it to a specific disease process or biomechanical disorders (6). Some studies divide AKP into two big groups being functional and mechanical causes (7). A detailed patient history and physical examination are critical in determining a diagnosis of AKP. There are still no clear objective criteria for diagnosis of AKP. There is however a consensus that peripatellar pain (within or about the knee) is a common symptom. Some studies include patients who complain of pain at the front and centre of the knee as their study subjects (5). Anterior knee pain in this study was defined as pain at the front and centre of the knee as complained by the patient. This has been associated

with certain limitations and pain aggravated by certain daily activities such as using the stairs, prolonged flexion and standing from a sitting position. Fortunately, most of these cases are of nondisabling nature and patients still maintain acceptable function of the knee (8).

Anterior knee pain causes mild to moderate pain which is commonly assessed via visual analogue scale in most cases. Sensi et al. in their study reported an incidence of 8 % for AKP after primary total knee arthroplasty (7). Other articles state that up to 45% of post total knee arthroplasty patients have residual AKP (9). This shows that AKP has a wide range of incidence and may affect up to half of the patients who have undergone total knee arthroplasty.

A multitude of factors have been researched with regards to the prevalence of AKP. Common causes of AKP that are actively being investigated currently are usually subdivided into patient characteristics, knee specific characteristics, prosthetic designs, operative techniques, treatment of patella and time of assessment.

Patient characteristics that are often analysed include weight, height and body mass index with studies showing variable results. Waters *et al.* found significant difference in weight between those that had AKP and those that did not (10). Picetti *et al.*107 performed a study of 100 knee arthroplasties, all without patellar resurfacing such as in our study, and found that higher weight and taller height is associated with higher incidence of AKP (10). This shows that patient characteristics may be a contributing factor to the development of AKP. If a link is established, optimization of weight prior to surgery may significantly reduce the incidence.

When discussing about time of assessment a retrospective study showed most AKP occurred early following arthroplasty. In half of the cases the knee remained painful from the time of surgery, more than a third became symptomatic after one year following surgery and only in 12.7%, the symptoms emerged more than 5 years since the operation (8). A study by Peng *et al.* found that

there was no correlation between assessment of post operative AKP and function in the presence of pre operative AKP (10).

Treatment of the patella in regards to resurfacing or not and its relation to AKP is also being widely investigated with fierce debate and no clear benefits of one method over the other. Advocates of patellar resurfacing claim reduced incidence of AKP, avoidance of second procedure to resurface, better patient satisfaction, lower rate of revision procedures, and improved cost-effectiveness (11). Adversaries for resurfacing claim it avoids complications related to resurfacing such as aseptic loosening, extensor mechanism injuries, overstuffing and osteonecrosis. This group also claim that there were no advantages in terms of pain, function, or satisfaction to routine patellar resurfacing (11). They further support their stand by the fact that secondary resurfacing procedures done to alleviate AKP does not show significant improvement in symptoms or patient satisfaction (11). The most extensively studied aspect of AKP currently has been the resurfacing of the patella. Many studies that focused on patella resurfacing show mixed results, with some showing no difference, some showing improved results with resurfacing and some even advice against doing it (1). With no concrete evidence to advise for or against resurfacing, it leaves the surgeon to decide whether to always resurface, never resurface or selectively resurface on a case-to-case basis.

It can be concluded that AKP after TKA can be seen as the presenting symptom of a multifactorial problem (1). Several factors may contribute to the problem and no single variable is likely to explain the differences in the reported rates of AKP, although variables resulting in abnormal patellofemoral joint loading appear to be of special significance (2). Several reports indicate that up to 12% of TKA revisions are due to patello-femoral dysfunction (2). These patello-femoral complications are thought to be caused by several factors such as errors in operative technique, inferior prosthetic design, components overstuffing, and excessive patello-femoral loads (9).

2.3.2 OVERWEIGHT AND OBESITY IN MALAYSIA

Malaysia has the highest rate of obesity and overweight among Asian countries with 64% of male and 65% of female population being either obese or overweight (12). There has been a great increase in these in values when compared to data five years ago. The Malaysian National Health and Morbidity Survey study conducted also shows a rising trend in the number of people who are overweight and obese (13). According to the World Health Organization (WHO), overweight and obesity are defined as abnormal or excessive fat accumulation that pose a risk to health. Body mass index (BMI) is used as a crude measure of obesity. It is calculated by taking a person's weight, in kilograms, divided by their height, in meters squared, or BMI = weight (in kg)/ height^2 (in m^2). The WHO criteria for Body Mass Index (BMI) classifies a BMI of 25-29.9 kg/m2 as overweight and >30 kg/m2 as obese (13). The normal BMI being 18.5 – 24.9 kg/m2, with those below 18.5 kg/m2 classified as underweight.

We do know that BMI does overestimates obesity in individuals who have high muscle mass and underestimates it in the older population who have lower body mass (14). However, it still is the most widely used index for obesity (14). Joint structures are adversely affected by the added weight in overweight and obese individuals due to the increase in joint reaction force (3). This increased weight is the mechanical hypothesis in pathogenesis of knee osteoarthritis which is more common or presents earlier in obese individuals. The patellofemoral joint which is of interest in this study, has also been proven to be burdened by the extra weight in the higher BMI groups. Increasing degrees of knee flexion increases retropatellar load which can be up to 3.3 times total body weight at 60 degrees of knee flexion (3). There is a relative risk of 2.76 and 4.2 for overweight and obese men respectively to be burdened by osteoarthritis of the knee and hip, while for women it is 1.8 and 1.96 respectively (15).

Obesity has also known to increase the risk of osteoarthritis and also complications post total knee arthroplasty. The higher incidence of osteoarthritis in overweight and obese patients coupled with the higher risk of unsatisfactory outcomes such as anterior knee pain post operatively makes this an interesting topic of study.

2.4 OBJECTIVE

1. To identify incidence of anterior knee pain post total knee arthroplasty at Hospital Universiti Sains Malaysia.

2. To determine association between BMI and incidence of anterior knee pain in patients post total knee arthroplasty.

2.5 STUDY DESIGN

This study will be a retrospective cohort which includes patients post total knee arthroplasty in HUSM from January 2018 to June 2020. The study population will include all patients who undergo total knee arthroplasty in the stipulated time and meet the inclusion criteria. The subjects will then be divided according to their BMI groups and the presence of anterior knee pain will be obtained from medical records during clinic follow up. Presence of anterior knee pain will be assessed up to 1 year post operatively. Data will then be analysed to determine a correlation. Researchers involved will adhere to the principles of the Declaration of Helsinki and the Malaysian Good Clinical Practice Guidelines. This study is self-sponsored.

2.6 STUDY AREA

The study location is in Hospital Universiti Sains Malaysia located in Kubang Kerian, Kelantan.

2.7 STUDY POPULATION

All patients who underwent total knee arthroplasty in HUSM from January 2018 to June 2020.

2.8 SELECTION CRITERIA

A. Inclusion criteria

1. Patients more than 40 years of age who underwent primary total knee arthroplasty for a primary diagnosis of osteoarthritis at Hospital Universiti Sains Malaysia

2. Have complete medical records to obtain the needed data

3. Unilateral and/or Bilateral Knee Arthroplasty

B. Exclusion criteria

1. Secondary knee osteoarthritis

2. Uni-compartmental knee arthroplasty

2.9 SAMPLE SIZE CALCULATION

For objective 1, sample size was calculated via single proportion method using Sample Size Calculator v2.0 (Excel format) as detailed below.

1 proportion – Estimation		
Proportion (p)	10.00%	
Precision	8.00%	
Significance level (α)	0.050	Two-tailed
Drop-out	5%	
Sample size	55	
Sample size (with drop-out)	58	

Naing, N. N. (2003). Determination of Sample Size. The Malaysian Journal of Medical Sciences: MJMS, 10(2), 84–86.

"Of the 100 knees, in 10 knees there was anterior knee pain."

(Early Results of Total Knee Replacements: "A Clinical and Radiological Evaluation". K.S. Dhillon, FRCS, Jamal, MS, S. Bhupinderjeet, MBBS. Med J Malaysia Vol 48 No 4 Dec 1993.) (16)

Although it is a retrospective study, a five percent drop-out rate was used to cater for a percentage of medical records with missing or incomplete date.

For Objective 2, sample size calculated using Chi Square Analysis with two proportions using the Power & Sample Size Calculator Program as detailed below.

"21.7% belonged to the healthy group while 40.2% formed the pre-obese group and the remaining 38.1% were in the obese group."

(A Prospective Study of Functional Outcome In 254 Total Knee Arthroplasty (TKA) And Predictive Factors in Age of Presentation. Vijay Kumar NK; *et al*. Asia Pacific Arthroplasty Society.) (17)

2.10 RESEARCH TOOL

To gain all the required information for the study, data from the below were required which are:

1. Medical records from HUSM

2. Data collection sheet

2.11 DATA COLLECTION METHOD

We will perform a retrospective review of clinical data from patient's clinical file traced from medical record office, HUSM. Data will be recorded in a prepared data collection sheet prior to be entered into the Excel and then SSPS system for analysis.

All study data will be kept for 2 years of time for usage and reference, after that it will be disposed. Patient's details and other relevant personal information will remain confidential and will not be used for in any presentation or publications. Details and data in publications will contain only patient's results and will not single out any individual that has participated in the study.

Two years of duration will be taken for this whole study to be completed, proposal drafting for 3-months, proposal presentation and Ethical board approval for 6 months, 12 months for data collection and data analysis followed by write-up for another 6 months.

NO: _____

RN:

Diagnosis: *primary OA or others*

Date of Surgery:

1.	Age (at surgery in years):	
2.	Sex:	Male / Female
3.	Height (meters):	
4.	Weight (kg):	
5.	BMI kg/m^2:	
6.	Diabetes Mellitus:	Yes / No
7.	ASA:	I / II / III / IV
8.	TKR site:	Right / Left / Bilateral
9.	Implant type:	CR / PS
10.	Patella Replacement	Y / N
11.	Anterior Knee Pain:	Yes / No
12.	Onset of pain: (months since operation date)	
13.	Treatment (If AKP Present)	
14.	Other Complications	

2.12 DATA ANALYSIS

Data analysis will be performed to explore and verify our hypothesis to answer the research questions. Data form the data collection sheet will be entered into excel spreadsheet and the statistical analysis will be done using SPSS version 24. Descriptive statistic will be performed to describe the sociodemographic characteristics.

Objective 1 will be calculated using frequency and percentage. Objective 2 will be analysed using Fisher exact test to determine the association between BMI and incidence of anterior knee pain. Other variables analysed with regards to anterior knee pain were done using Fisher exact test for categorical data (gender, alignment, side, insert thickness) and Independent T test was used to compare mean of the numerical data (height, weight). We consider p value less than 0.05 to be statistically significant, with 95% of confidence interval.

2.13 BENEFIT OF STUDY

This study finding will help determine the complication rate at our center compared to other centers as reported and may be used as a measure of quality. The results of this study can contribute more information and data for further research in this topic. The association of anterior knee pain with body mass index can provide evidence to further motivate patients on importance of obtaining optimum body mass index prior to undergoing surgery. This study may elevate the name of Hospital Universiti Sains Malaysia as a trusted centre for joint replacement surgery.

2.14 ETHICAL CONSIDERATION

1. Privacy and confidentiality

   a. The subject's data will be obtained retrospectively from the medical records with the permission of the hospital director and ethical committee team. There is no direct contact with the subject's nor any effect to the patient's management and care as data is obtained retrospectively from medical records only.

2. Declaration of absence of conflict of interest

   a. Hereby as a principal investigator of this study, would like to declare myself as a non-beneficial party of the study and it is done solely for an academic purpose only.
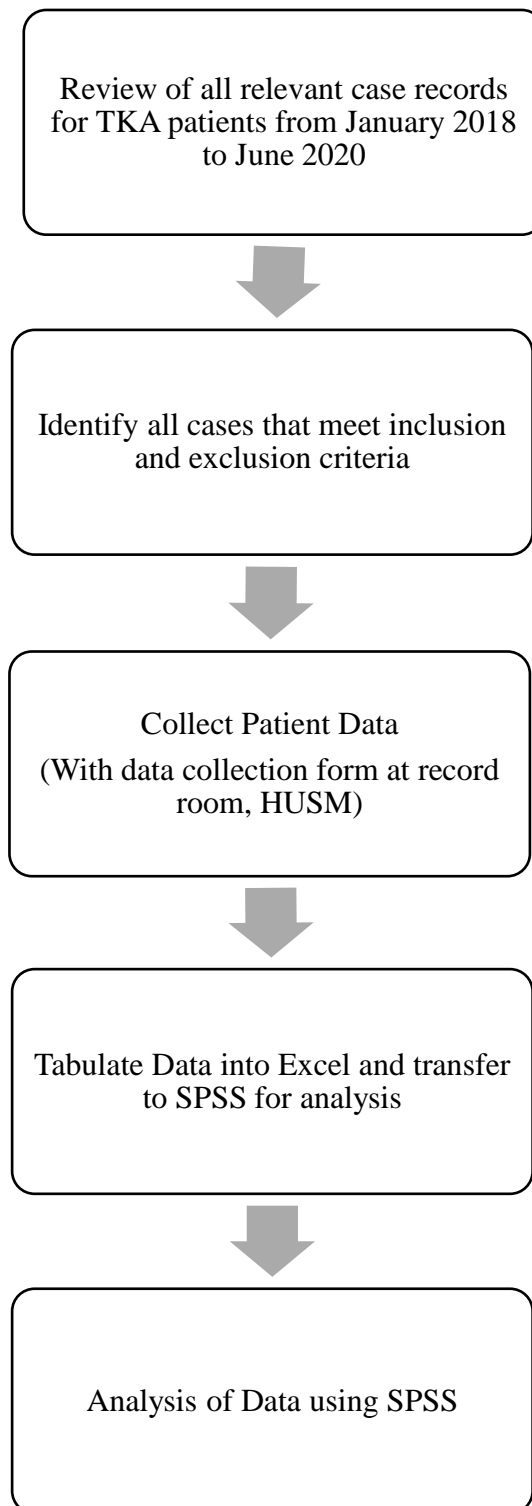
3. Honorarium and incentives

   a. This study is not bound to any form of research grant and any minor portion of spending will be borne by the principal researcher.

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Flow Chart of Study

Review of all relevant case records for TKA patients from January 2018 to June 2020

Identify all cases that meet inclusion and exclusion criteria

Collect Patient Data

(With data collection form at record room, HUSM)

Tabulate Data into Excel and transfer to SPSS for analysis

Analysis of Data using SPSS

Gantt Chart

Timeline	December 2021-June 2022	May – June 2022	July 2022	August 2022	September - October 2022	October - November 2022	December 2022
Data Collection	███						
Data Processing		███					
Statistical Analysis			███				
Final Review				███			
Supervisor					███		
Review						███	
Approval Process							███

ETHICAL APPROVAL LETTERS:

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan
16150 Kubang Kerian, Kelantan. Malaysia.
Tel. : +609 - 767 3000/2354/2362
Fax. : + 609 - 767 2351
Email : jepem@usm.my
Laman Web : www.jepem.kk.usm.my
www.usm.my

28th January 2021

Dr. Ganesha Devan Kanagarajah
Department of Orthopaedics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code   : USM/JEPeM/20110559
Protocol Title : Incidence of Anterior Knee Pain Post Total Knee Arthroplasty in Correlation with BMI.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code USM/JEPeM/20110559, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from 28th January 2021 until 27th January 2022.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:
1. Prof. Dr. Amran Ahmed Shokri

The following documents have been approved for use in the study.
1. Research Proposal

In addition to the above mentioned document, the following technical documents were included in the review on which this approval was based:
1. Data Collection Form

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.
3. Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.
4. Reports of adverse events including from other study sites (national, international) using the JEPeM-USM FORM 3(G) 2019: Adverse Events Report.
5. Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(E) 2019.
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using JEPeM-USM FORM 3(C) 2019: Final Report Form.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

06th December 2021

Dr. Ganesha Devan Kangarajah
Department of Orthopaedics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM USM Code: USM/JEPeM/20110559

Study Protocol Title: Incidence of Anterior Knee Pain Post Total Knee Arthroplasty in Correlation with BMI.

Dear Dr.,

We wish to inform you that Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) acknowledged receipt your application for continuing review dated 10th November 2021.

Upon review of JEPeM-USM Form 3(B) 2021: Continuing Review Application Form, the committee AGREED for the EXTENSION OF APPROVAL (commencing on 28th January 2022 to 27th January 2023). The report is included in the protocol file.

Thank you for your continuing compliance with the requirements of the JEPeM-USM.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Sincerely,

ASSOC. PROF. DR. AZLAN HUSIN
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

c.c   Secretary
       Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
       Universiti Sains Malaysia