COMPARING RADIOLOGICAL UNION BETWEEN SINGLE SPIRAL BLADE PROXIMAL FEMORAL NAIL AND DOUBLE INTEGRATED LOCKING SCREWS PROXIMAL FEMORAL NAIL IN TREATING TROCHANTERIC FEMUR FRACTURES WITH RUSH SCORING SYSTEM

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ABSTRAK

Pengenalan

Implan cephalomedullary seperti ‘proximal femoral nail’ adalah salah satu implan yang kerap digunakan untuk merawat patah tulang bahagian ‘trochanteric femur’. Implan jenis ini telah dibuktikan lebih stabil secara biomekanik dalam merawat patah-patah trochanteric femur yang tidak stabil berbanding dengan implan extramedullari. Walau bagaimanapun penilaian xray untuk menilai penyembuhan secara operatif tidak biasa diukur. Skor RUSH di sisi lain adalah sistem pemarkahan yang telah disahkan sebelum ini untuk menilai penyembuhan tulang di dalam xray untuk patah tulang bahagian femur proksimal.

Matlamat Kajian

Untuk membandingkan penyembuhan patah tulang dari segi radiologi dengan menggunakan skor RUSH di antara ‘single spiral blade proximal femoral nail’ (PFNA) dan ‘double integrated locking screws proximal femoral nail’ (INTERTAN) dalam merawat patah tulang patah tulang di Hospital Tengku Ampuan Rahimah Klang dan menilai komplikasi intraoperatif yang timbul di kedua-dua kumpulan

Metodologi

Kajian retrospektif komparatif pada 74 pesakit yang mengalami keretakan tulang proksimal femur dan menjalani pembedahan implan femoral proksimal. Sinar x mereka pada 6 minggu, 12 minggu dan 24 minggu telah diambil bersama dengan folder mereka dan dikaji semula untuk skor RUSH oleh 2 aksesori berbeza . Data sosiodemografi dan komplikasi intraoperatif telah dicatat dan direkodkan. Skor RUSH untuk kedua-dua kumpulan telah ditabulasi dan kemudian

dianalisis untuk melihat perbezaan statistik yang signifikan dalam kadar kesatuan dari segi skor RUSH.

Keputusan

Apabila dibandingkan dalam setiap kumpulan, kedua-dua PFNA dan INTERTAN, terdapat perubahan min signifikan dalam skor RUSH pada setiap masa. [F Pillai's Trace (df) = 1194.00 (2,71), P <0.001]. Apabila membandingkan skor min pada 6 minggu, 12 minggu dan 24 minggu antara satu sama lain dengan menggunakan perbandingan berpasangan, terdapat perubahan signifikan min skor RUSH dalam semua perbandingan masa (P <0.001) untuk kedua-dua kumpulan. Kumpulan INTERTAN mempunyai skor RUSH yang lebih tinggi berbanding dengan kumpulan PFNA pada setiap masa [F (df) = 6.32 (1,72), P = 0.014. Walau bagaimanapun tidak terdapat perbezaan yang signifikan antara 2 kumpulan dari segi kesan interaksi masa kumpulan. [F Pillai's Trace (df) = 2.82 (2,71), P = 0.066]

Rumusan

INTERTAN mempunyai pemarkahan RUSH yang lebih baik dalam semua 3 tempoh masa dan keseluruhannya jika dibandingkan dengan PFNA. INTERTAN adalah implan yang lebih baik dalam merawat patah tulang femur trochanterik apabila ia berkaitan dengan penyembuhan dari segi xray.

Kata kunci : Patah tulang Femur bahagian Trochanter, Implan Proximal Femoral Nail (PFNA), Intertan Nail, Kadar Penyembuhan, Skor RUSH

ABSTRACT

Introduction: Proximal femoral nails are one of the most commonly and preferred used cephalomedullary implant used to treat trochanteric region femur fractures. These nails have shown to be more biomechanically stable in unstable trochanteric fractures compare to the extramedullary devices. However the assessment of radiological union on radiographs post operatively is not commonly measured. RUSH scoring on the other hand is a previously validated scoring system for assessing radiological union in proximal hip fractures.

Aim: To compare the radiological union using RUSH score between the single spiral blade proximal femoral nail (PFNA) and the double integrated locking screws proximal femoral nail (INTERTAN) in treating trochanteric femur fractures in Hospital Tengku Ampuan Rahimah Klang and assess intraoperative complications arising in both the groups.

Methodology: A retrospective study comparing 2 group of patients with trochanteric femur fractures who underwent 2 types of proximal femoral nails. Total of 74 patients with 37 patients in each arm were included in this study. Their post-operative x-rays at 6 weeks, 12 weeks and 24 weeks were taken together with their folders and reviewed for RUSH scoring by 2 different accessors. The sociodemographic data and the intraoperative complications were noted and recorded. The RUSH scores for both the groups were tabulated and then analysed to see any statistical significant difference in union rates in terms of RUSH scores.

Results: When compared within each group, both the PFNA and the INTERTAN, there was a significant change of mean in RUSH score at every follow up. [F Pillai's Trace(df)=1194.00 (2,71), P<0.001]. When comparing the mean score at 6 weeks, 12 weeks and 24 weeks with each other using pairwise comparison, there is a significant change of mean of RUSH score in all time comparison (P<0.001) for both the groups. INTERTAN group has a significant higher mean of RUSH score compare to PFNA group at all periods of time [F(df)=6.32(1,72), P=0.014. However there was no significant difference between the 2 groups in terms of group time interaction effect. [F Pillai's Trace(df)=2.82 (2,71), P=0.066].

Conclusion: INTERTAN had a better RUSH scoring in all 3 periods of time and in overall when compared to the PFNA. The INTERTAN is a better implant in treating trochanteric fractures in terms of faster union.

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Keywords

Trochanteric Femur fracture, Proximal Femoral Nail (PFNA), INTERTAN Nail, Rate of Radiological Union, RUSH Score

CHAPTER 1

INTRODUCTION

1.1 Introduction

In the current trend of trauma cases, proximal femur fractures are very common. Proximal femur fractures can consist of neck of femur fractures, trochanteric femur fractures which can be further subdivided to intertrochanteric region and subtrochanteric region fractures. Traumatic fractures to the femur does not only include high energy trauma in origin but also trivial falls and injuries in the elderly age group. In the elderly, it commonly causes proximal femur fractures such as the neck and the trochanteric region. Proximal femur fractures in the elderly and the young has always been a challenge for the orthopaedic surgeons all around the world. Many implants have been developed to treat the trochanteric fractures from the extramedullary plates and screws to the more stable cephalomedullary nails. Both cephalomedullary nails (CMN), and sliding hip screws (SHS) are utilized as the standard of care for fixation of these fractures. Operative management with either fixation device allows for early rehabilitation and decreased morbidity and mortality. However in recent journals, cephalomedullary nails have shown to be more biomechanically stable in unstable intertrochanteric fractures compare to the extramedullary device such as the sliding hip screw.

The history of cephalomedullary nails started way back in 1940s when Ernst Pohl designed the first prototype of intramedullary implant for osteosynthesis of trochanteric fractures. This first prototype was known as the “YNagel”.]. Later in 1986, Grosse, Tanglang and Kempf, developed the successor to the original Ernst Pohl’s company, the so-called Gamma nail. This nail was the most widely used intramedullary device to treat trochanteric fractures worldwide at this period of time. As many authors started reporting complications from this implant, slowly this complications were addressed and upgraded to the current proximal femoral nail. Currently there are many designs with various modifications of the proximal femoral nail.

One of the recent implants used and being introduced is the proximal femoral nails which one of them uses one spiral helical blade fixation to the femoral neck and the other one uses 2 cephalocervical screws to purchase the femoral neck. Both nails has got its advantages in rotational stability, anti varus collapse. Both devices are types of cephalomedullary devices in the fixation of proximal femur fractures. These cephalomedullary device fixations allows for improved purchase in the femoral head by radial compaction of the cancellous bone around the blade during insertion. The helical neck blade has the advantages of fixation stability, antirotation, and antivarus collapse. Similarly, a new device, the InterTan nail, uses 2 cephalocervical screws in an integrated mechanism allowing linear intraoperative compression and rotational stability of the head-neck fragments.

The assessment of fracture healing following intertrochanteric fracture fixation is highly variable with no validated standards. Agreement with respect to fracture healing following surgery is important for optimal patient management. While intertrochanteric fracture agreement studies have largely focused on fracture classification systems, little has been published evaluating fracture healing assessments. Radiological Union Score for hip (RUSH) scoring system provides a standardized healing assessment for hip fractures. It has been previously used to assess femoral neck fractures as well intertrochanteric fractures of the femur. Although not so widely used, its method of assessing fracture healing by bridging callus and disappearance of fracture line is a validated scoring system. Ability to identify fractures that have not healed is important for defining nonunion in clinical trials and predicting patients who will likely require additional surgery to promote fracture healing. Aim of this study is to compare two types of implants and assess radiological union in both the groups using a standardized scoring system (RUSH) in similar kind of fractures. Assessment will involve radiological union achieved from both the implants within the period of 6 months

Chapter 2

OBJECTIVES

2.0 General Objective

To compare the radiological union using between single spiral blade proximal femoral nail (PFNA) and double integrated locking screws proximal femoral nail (INTERTAN) in treating trochanteric fractures of the femur.

2.1 Specific Objectives

2.1.1 To determine intraoperative complications that commonly arise between both the implants groups.

2.1.2 To determine the radiological union between both the groups using RUSH score, a scoring used in fracture healing assessment for hip fractures

Chapter 3

MANUSCRIPT

3.1. TITLE: COMPARING RADIOLOGICAL UNION BETWEEN SINGLE SPIRAL BLADE PROXIMAL FEMORAL NAIL AND DOUBLE INTEGRATED LOCKING SCREWS PROXIMAL FEMORAL NAIL IN TREATING TROCHANTERIC FEMUR FRACTURES USING RUSH SCORING SYSTEM.

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3.2 ABSTRACT

Introduction: Proximal femoral nails are one of the most commonly and preferred used cephalomedullary implant used to treat trochanteric region femur fractures. These nails have shown to be more biomechanically stable in unstable trochanteric fractures compare to the extramedullary devices. However the assessment of radiological union on radiographs post operatively is not commonly measured. RUSH scoring on the other hand is a previously validated scoring system for assessing radiological union in proximal hip fractures.

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3.3 INTRODUCTION

In the current trend of trauma cases, proximal femur fractures are very common. Proximal femur fractures can consist of neck of femur fractures, trochanteric femur fractures which can be further subdivided to intertrochanteric region and subtrochanteric region fractures. Traumatic fractures to the femur does not only include high energy trauma in origin but also trivial falls and injuries in the elderly age group. In the elderly, it commonly causes proximal femur fractures such as the neck and the trochanteric region. Trochanteric fractures are among the major causes of mortality and morbidity in elderly individuals. The aim of treatment is to perform surgery as soon as possible to allow early mobilization [1,2]. Several implant designs have been developed in an attempt to aid fracture fixation, facilitate early ambulation and reduce the risk of complications with improved functional outcomes when treating these trochanteric fractures [3,4]. Currently we have extramedullary devices as well intramedullary devices. Intramedullary devices such as the cephalomedullary nails (CMN), are utilized as the standard of care for fixation of these fractures. Operative management with either fixation device allows for early rehabilitation and decreased morbidity and mortality. However in recent journals, cephalomedullary nails have shown to be more biomechanically stable in unstable intertrochanteric fractures compare to the extramedullary device such as the sliding hip screw [5].

The history of cephalomedullary nails started way back in 1940s when Ernst Pohl designed the first prototype of intramedullary implant for osteosynthesis of trochanteric fractures. This first prototype was known as the “Y Nagel” [6]. The Y-Nail was used in Germany until the 1970s, but never found popularity in other countries. Later in 1986, Grosse, Tanglang and Kempf, developed the successor to the original Ernst Pohl’s company, the so-called Gamma nail [6]. This nail was the most widely used intramedullary device to treat trochanteric fractures worldwide at this period of time. As many authors started reporting complications from this

implant, slowly this complications were addressed and upgraded to the current proximal femoral nail. Currently there are many designs with various modifications of the proximal femoral nail.

For example, the Proximal Femoral Nail Antirotation (PFNA) [Synthes, Solothurn, Switzerland] [7] is a modification of older version of the Proximal Femoral Nail, uses helical neck blade fixation to the femoral neck. The helical neck blade has the advantages of fixation stability, antirotation, and antivarus collapse [8]. This cephalomedullary device fixations allows for improved purchase in the femoral head by radial compaction of the cancellous bone during insertion of the blade which allows additional anchoring which is important when dealing with osteoporotic bone. Similarly, the newer device, the double integrated locking screws proximal femoral nail (INTERTAN) [Smith–Nephew, Memphis, TN], uses 2 cephalocervical screws in an integrated mechanism allowing linear intraoperative compression and rotational stability of the head-neck fragments[9]. For the INTERTAN nail the worm gear mechanism converts rotation to active compression force while stabilizing the fractured segments. The integrated screw mechanisms together generate a push and pull force that holds the compression after instruments are removed and eliminate the Z effect. [9,10] Both nails has got its advantages in rotational stability and anti varus collapse.

The assessment of fracture healing following intertrochanteric fracture fixation is highly variable with no validated standards. While intertrochanteric fracture agreement studies have largely focused on fracture classification systems, little has been published evaluating fracture healing assessments [11]. The tool that was used in our study to measure the radiological union was the RUSH score. It provides a standardized healing assessment for hip fractures. It has been previously used to assess femoral neck fractures as well intertrochanteric fractures of the femur. The RUSH scoring system for radiographic union is a recently developed radiographic scoring system from the University of Toronto and McMaster University. This team developed

2 scoring systems which are the radiographic union score for hip (RUSH) and radiographic union score for tibia (RUST). The RUSH score quantifies four measures of healing: cortical bridging, cortical fracture disappearance, trabecular consolidation, and trabecular fracture disappearance [12]. Cortical healing is assessed in four anatomic femoral neck regions; anterior, posterior, medial, lateral (Figure 1) and trabecular healing is measured with two assessments; fracture line disappearance and consolidation of matrix (Figure 2). Each of the 10 assessed dimensions of radiographic femoral neck healing are scored 1 to 3, leading to a minimum score of 10 indicating no signs of healing and a maximum score of 30 which means perfect healing.[13]. A study by Daniel Maiettini et al in 2016 where intertrochanteric femur fractures were treated using intramedullary nails and fracture union assessment was done by studying the correlation between the RUSH score and the Visual Analogue Score (VAS) at 40 days and 90 days post op. This study was performed to evaluate the feasibility of RUSH scoring when treating intertrochanteric femur fractures using intramedullary nails. It was reported that the pain score for the patients has reduced inversely as the RUSH score increased at 40 days and 90 days follow up. The significant correlation between RUSH and VAS scores confirms the efficacy and feasibility of the RUSH scoring system in predicting bone healing during patient follow-up [14].

Similarly, RUSH scoring system was mentioned in a literature review by Saam Morshed in the current options in assessing fracture union. He referred to the study done by Bhandari et al where 150 cases of femoral neck fractures were reviewed at two time points to determine inter-rater and intra-rater agreement. This was led by a panel of three radiologists and three orthopaedic surgeons to evaluate if agreement can be achieved between 2 group of panels which consist of radiologist and orthopaedic surgeons. Inter-rater agreement for the overall subjective impression of fracture healing between reviewer groups was only fair (intraclass coefficient [ICC] = 0.34, 95 % CI: 0.11–0.52. Use of the RUSH score improved overall

agreement between groups to substantial (ICC=0.66, 95 % CI: 0.53–0.75). This proofs that the RUSH score improves agreement of fracture healing assessment between orthopaedic surgeons and radiologists and offers a systematic approach in evaluating intertrochanteric hip fractures. [15]

Although not so widely used, its method of assessing fracture healing by bridging callus and disappearance of fracture line is a validated scoring system. Ability to identify fractures that have not healed is important for defining non-union in clinical trials and predicting patients who will require re surgery. Aim of this study is to compare these two types of implants and assess the radiological union in trochanteric types of fractures in both the groups using a standardized scoring system (RUSH). Assessment will involve radiological union achieved from both the implants within the period of 6 months. The radiological union scores will be evaluated in terms of mean scoring between both the groups. We wanted to also study the intraoperative complications that arise from both these types of implants and to explore the sociodemographic data from both the groups.

3.4 MATERIALS AND METHODOLOGY

Study Population

This study was conducted solely in Hospital Tengku Ampuan Rahimah, Klang between Jan 2016 till June 2017. It's a retrospective comparative study to compare two implants on radiological union. All of the 85 patients who were included in this study are those who presented to this hospital with intertrochanteric and subtrochanteric femur fractures or was referred to this centre for the similar problems. This study has been approved by the ethics committee of Universiti Sains Malaysia (JEPEM) and the National Medical Research Registry of Malaysia (NMMR).

Inclusion and Exclusion Criteria

All cases of subtrochanteric fractures and intertrochanteric requiring a proximal femoral nail were considered eligible for the study. Inclusion criteria includes all those patients who are above 18 years of age, those who are also associated with upper limb injuries and bilateral trochanteric femur fractures. Patients with any pathological fractures excluding osteoporosis, patients with severe head injury and patients with open fractures were excluded from this study.

Assessment Methods

Those patients who underwent proximal femoral nail surgery either with single spiral blade proximal femoral nail (PFNA) or double integrated locking screws proximal femoral nail (INTERTAN) will be traced retrospectively from the operating theatre census logbook throughout the period of the study. After obtaining the names of the patients together with their registration numbers, folders of these patients with the x-rays are traced from the records office. The patients' folders were reviewed by the principal investigator to collect the sociodemographic data and intraoperative complications. The patients postoperative x-rays at 6 weeks, 12 weeks and 24 weeks were reviewed by the investigator according to the RUSH scoring method and recorded in performa sheets. A second set of performa was given to an orthopaedic surgeon who is from the same hospital which the study is being conducted. He was given the set of performa together with the same set of x-rays. This is to prevent bias in the RUSH score interpretation. Results from both the reviewers were collected and compiled into SPSS for statistical analysis. The mean results of RUSH score obtained from both sets of performa was used for the statistical analysis of later in the study.

Statistical Analysis

The main research question in this study was if there is a difference in mean score between both these implants in relation to RUSH scoring. RUSH scoring was compared between both these implants in a series of time which was at 6 weeks, 12 weeks and 24 weeks post operatively. In this study there were total of 3 types of analysis applied. The demographic data like the diagnosis, complications and duration of time taken for each surgery was analyzed using descriptive analysis. Secondly univariate analysis using independent T test was used to study the mean duration, mean complications rate and the diagnosis comparisons between both

these groups. Finally, multivariate analysis which is the repeated measure ANOVA (RMANOVA) method was used to evaluate the significant mean difference in between both the groups. The advantage of using RMANOVA was, the investigator was able to study in detail of a few more statistics like was there any significant mean difference of RUSH score within groups of implants based on time and regardless of time.