ACCELERATED HIP FRACTURE SURGERY IN THE ELDERLY: A PILOT STUDY

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ACCELERATED HIP FRACTURE SURGERY IN THE ELDERLY: A PILOT STUDY

ABSTRACT

BACKGROUND: The rising incidence of hip fractures in the elderly is a healthcare burden in terms of morbidity, mortality and costs that can be reduced by accelerating surgery. Hip fractures initiate an inflammatory response, resulting in a catabolic, procoagulant, stressed state that may result in further complications in an already vulnerable, immobile group of patients. Hastening surgery shortens the duration of the body's exposure to these harmful states and may reduce complications and improve patient outcome.

OBJECTIVES: The primary objective of this pilot study is to compare mortality rates and major peri-operative complications in patients who underwent accelerated surgery versus standard waiting times. The secondary objectives looked at length of hospital stay and time taken to mobilise after surgery.

METHODS: Patients who fulfilled the inclusion criteria such as age more than 45 years and diagnosed with a hip fracture were recruited. Patients were then randomly assigned to either an accelerated group who had surgery done within 6 hours of diagnosis or a standard group who followed standard operating times. These patients were then followed up to compare morbidity, mortality, time taken to mobilise after surgery, length of hospital stay and Functional Independence Measure mobility scores at 30-days.

RESULTS: There was statistical significance between the preoperative waiting time of the 2 groups (5.44 hours vs 51.05 hours, $p<0.001$). For the other measured variables, there were no statistically significant differences noted the 2 groups; time to mobilisation (25.17 hours vs 29.05, $p=0.450$), length of stay in hospital (6.11 days vs 6.58 days, $p=0.824$) and length of postoperative stay in hospital (5.89 days vs 4.37 days,

p=0.482) and 30 day FIM scores between the 2 groups (51.4 vs 58.88, p=0.390). Both groups had 2 cases of death among its subjects. In addition to the deaths, 1 subject in the accelerated group was complicated with a surgical site infection while 1 subject had a periprosthetic hip fracture in the standard group. However, there was no significant differences in the 30-day perioperative complications rate between the 2 groups (16.7% vs 14.3%, p=1.000).

CONCLUSION:This pilot study revealed the feasibility to conduct accelerated surgery on a larger scale to study the effect on 30-day perioperative complications, time to mobilisation, length of postoperative stay and 30-day FIM scores.

ACCELERATED HIP FRACTURE IN THE ELDERLY: A PILOT STUDY

ABSTRAK

LATARBELAKANG: Insiden patah pinggul di kalangan warga tua merupakan satu beban dari segi morbiditi, kematian dan cost kepada institusi kesihatan. Beban ini diharapkan berkurangan sekiranya pembedahan untuk merawat pesakit yang mengalami patah sendi pinggul. Badan warga tua yang mengalami patah sendi pinggul bukan sahaja terpaksa terlantar atas katil dan kurang pergerakan akan ada respons keradangan yang mengakibatkan pesakit berada dalam status katabolik, senang mendapat penyakit darah beku dan mengalami tekanan. Pembedahan awal akan mengurangkan pendedahan kepada respons keradangan ini dan mengurangkan kemudaratan kepada pesakit.

OBJEKTIF: Matalamat kajian ini adalah untuk meneliti kadar kematian dan komplikasi pembedahan di antara para pesakit yang menjalankan pembedahan awal yang sengaja dipercepatkan (‘accelerated’) jika dibandingkan dengan pesakit yang mejalankan pembedahan mengikut waktu menunggu yang biasa (‘standard’). Matlamat kajian ini juga meninjau masa untuk pesakit bangun bergerak selepas pembedahan dan tempoh rawatan di hospital.

KAEDAH: Pesakit yang memenuhi kriteria seperti usia lebih daripada 45 tahun dan mengalami patah sendi pinggul akan dijemput mengambil bahagian dalam kajian ini. Pesakit akan ditentukan secara rawak untuk sama ada menjalankan pembedahan dalam tempoh enam jam atau mengikut secara elektif. Para pesakit akan dikaji untuk membandingkan kadar kematian, komplikasi, tempoh masa yang diperlukan untuk mula pergerakan selepas pembedahan, tempoh masa diwadkan di hospital dan skor pergerakkan (Functional Independence Measure atau FIM) selepas 30 hari.

KEPUTUSAN: Tempoh masa menunggu sebelum pembedahan menunjukkan perbezaan statistik di antara dua kumpulan pesakit (5.44 hours vs 51.05 hours, $p<0.001$). Tiada perbezaan yang ketara dilihat dari segi; tempoh masa untuk

pergerakkan selepas pembedahan (25.17 hours vs 29.05, p=0.450), tempoh keseluruhan penginapan di hospital (6.11 days vs 6.58 days, p=0.824) and tempoh penginapan di hospital selepas pembedahan (5.89 days vs 4.37 days, p=0.482) and skor FIM (51.4 vs 58.88, p=0.390). Kadar kematian dan kadar komplikasi selama 30 hari selepas pembedahan adalah sama bagi kedua-dua kumpulan dan tiada perbezaan statistik (16.7% vs 14.3%, p=1.000).

RUMUSAN: Kajian perintis ini menunjukkan bahawa pembedahan awal dalam tempoh 6 jam boleh dijalankan pada skala yang lebih bermakna untuk mengkaji kadar komplikasi selama 30 hari selepas pembedahan.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF SYMBOLS AND ABBREVIATIONS

UMMC	:	University Malaya Medical Centre
IWRS	:	Interactive Web Randomization System
FIM	:	Functional Independence Measurement
PCI	:	Percutaneous Coronary Intervention
COPD	:	Chronic Obstructive Pulmonary Disease
POD	:	Postoperative Day

LIST OF APPENDICES

CHAPTER 1: BACKGROUND

The demographics of the population in Malaysia, is likely to follow the footsteps of other developed nations resulting in a rise in the elderly group of patients. With this shift in demographics, the sheer numbers of elderly patients admitted with various co-morbidities and treatable conditions need to be addressed to reduce the socio-economic costs and burden on healthcare. Hip fractures in the elderly due to falls or low impact trauma have a significant risk in terms of morbidity and mortality.

Hip fractures result in bed-ridden patients who need prompt surgery. This puts the patient in a vulnerable, dependent state compounded by stress, pain and loss of function. Complications from this include deep vein thrombosis, pulmonary embolism, myocardial infarct, stroke, orthostatic pneumonia and bedsores in the peri-operative period.

The current practice for surgery for closed hip fractures in Malaysia is planned as an elective list, usually more than 48 hours later. The reason for delay is due to limited resources such as operating theaters and staff. Delay is sometimes to allow for medical stabilisation of the elderly patient with severe co-morbidities where further investigations and a medical consult are warranted before surgery to predict risk mortality. Some patients may need reversal of anticoagulants and normalisation of coagulation screen to reduce risk of bleeding intraoperatively. In these high-risk patients, it would be prudent to delay surgery to allow for better planning. However, in relatively fit and stable patients, unnecessary delay results in increased morbidity and mortality rates and would not be justifiable.

Studies have shown significant reductions in morbidity, mortality and length of stay in patients who underwent early surgery. The timing and definition of early surgery has not been defined but benefits were seen in patients operated on within 24 to 72 hours.

The primary objective of this pilot study is to look at mortality rates and post-operative complications up to 30 days. The secondary objective of this study is to compare post-operative time taken for mobilisation and length of post-operative hospital stay. The rates of peri-operative complications such as stroke, myocardial infarct, deep vein thrombosis, and infection are postulated to be reduced. Early surgery also means shorter period of immobility and would allow the patient to regain mobility earlier.

CHAPTER 1: LITERATURE REVIEW

Hip fractures in the elderly present a major problem in terms of morbidity, mortality, healthcare and socioeconomic costs. With rising life expectancy globally and the expanding aging population, it is estimated that the incidence of hip fractures will rise from 1.66 million in 1990 to 6.26 million by 2050.[1]

Osteoporotic hip fracture is an established health problem in the West and is increasingly recognized as a growing problem in Asia.[2] As three-quarters of the world's population live in Asia, it is projected that Asian countries will contribute more than 50% to the pool of hip fractures in coming years by 2050.[1]

In Scandinavia and the United States, age-specific incidence rates of hip fractures have plateaued or decreased, the projected rise in hip fractures will be from Asian nations with the exceptions of Hong Kong and Taiwan where secular trends have been reported. [2,3,4]

In Malaysia, annual hip fracture rates range from 150-250 per 100000 for both sexes.[2] These numbers are projected to increase. A study looking at demographic patterns of patients sustaining hip fractures in Malaysia revealed that most hip fracture patients were 70 years and above, majority were female, and the main mechanism of injury was low energy trauma. [5]

With this expectant rise socioeconomic burden, strategies to prevent hip fractures and to find effective goals of treatment that reduce healthcare costs come into play. A study looking at inpatient cost for hip fracture in Singapore showed that if the surgery was delayed (i.e. > 48 hours after admission), every additional day of delay was found to result in a SGD 575.89 increase in cost. The average cost for the patients whose surgery was delayed was SGD 2,716.63 more than that of the patients who had surgery within 48 hours. [6]

A hip fracture results in pain, bleeding and immobility. These factors initiate inflammatory, hypercoagulable, catabolic and stress states that can precipitate medical complications.[7-13] Early surgery shortens the exposure to these harmful states and, therefore, may reduce morbidity and mortality. Earlier surgery may shorten the period of immobility, which may improve functional outcomes and reduce healthcare costs. A pilot trial conducted in 2014 consisting of 60 patients showed encouraging evidence that accelerated surgery have positive outcomes[14]

A systematic review and meta analyses in 2010 by Simunovic et al showed that early surgical treatment of hip fracture (< 24, < 48 or < 72 hours) was associated with a significant reduction in mortality by 19%. Earlier surgery was also associated with a reduced risk of pneumonia (risk reduction of 41% in 2 studies) and pressure sores (52% reduction in risk of pressure sores) as compared to those with delayed surgery.[15] In a recent review of 35 published studies involving 191 873 patients, Moja et al found that surgery conducted before 24 to 48 hours was associated with lower all-cause mortality, confirming earlier findings.[16]

However, some clinicians argue that patients underwent delayed surgery because they required stabilisation due to co-morbidities. A systematic review of 52 published studies involving 291 143 patients was recently performed showing that when studies adjusted for confounding factors, they were less likely to report improved survival outcomes from early surgery.[10] When adjusted for additional variables such as older age, dementia, and chronic comorbidities, they found that delaying surgery up to 5 days had no influence on mortality.[17] Based on their results, the authors concluded that patients with a poorer baseline health status underwent more delayed surgery and that this association alone accounted for the poorer outcomes in patients who had delays.

One retrospective study looked at a total of 139 119 medically stable patients with hip fracture who were aged 65 years or older and noted cumulative 30-day in-hospital mortality was 4.9% among patients who were surgically treated on admission day, increasing to 6.9% for surgery done after day 3.[18] The risk of complications and 30-day mortality risk were significantly higher when wait times were greater than 24 hours.[19] Another study involving 720 patients observed a linear relationship between surgical timing and 1-year mortality, adding that each 10-hour delay from admission to surgery was associated with an estimated 5% higher odds of 1 year mortality. This would suggest hip fractures need to be treated similarly to other time-sensitive pathology such as stroke and myocardial ischemia.[20]

Overall the benefits of early surgery would reduce length of stay and morbidity which translates into reduction in healthcare cost. Current management of hip fracture suggests that early surgery within 24 hours shows significant improvements in outcome.

CHAPTER 2: METHODOLOGY

A pilot cohort study will be conducted in University Malaya Medical Centre (UMMC Ethics approval no: 201512-1965) . The patient enrolment period will be over 25 months, from October 2016 to November 2018. Patients presenting with a closed hip fracture will be recruited from the emergency department after the diagnosis of a hip fracture was made.

Inclusion criteria for the study are patients age more than 45 years with a hip fracture from a low energy mechanism requiring surgery diagnosed during study hours. Exclusion criteria include emergent surgery or intervention for another reason, open, bilateral or peri-prosthetic fractures, therapeutic anticoagulation for which there is no reversal method, history of Heparin induced thrombocytopenia (HIT), current use of warfarin and INR > 1.5, refusal of participation or previous participation in the study. Suitable patients will then sign an informed consent agreeing to partake in the study, following which they will be randomly assigned to either an accelerated group or standard group using Interactive Web Randomization System (IWRS). The IWRS is a 24-hour computerized randomisation internet system maintained by the coordinating centre at the Population Health Research Institute (PHRI), which is part of Hamilton Health Sciences and McMaster University in Hamilton, Ontario, Canada. The randomisation process will use block randomisation stratified by centre and by the type of planned surgery (open reduction and internal fixation or arthroplasty). We will use randomly varying block sizes, and study personnel and investigators will not know the block sizes. Patients will be randomised in a 1:1 fashion to receive accelerated medical clearance and accelerated surgery versus standard care.

In the accelerated group surgery would be performed within 6 hours from the time of diagnosis. The standard group would then have a scheduled elective surgery according to standard waiting times. In the standard group, there will be no delay in treatment.

Patients will be recruited from the time of 4am to 4pm daily as we require surgeons, geriatricians, anaesthesiologists and cardiologists to give clearance for the recruitment. Each patient will be assessed individually and cleared for surgery prior to randomisation. The timing during working hours will also ensure easy access to source for extra staff to run an extra operating theatre if needed.

Post-operatively the patients will be followed up until discharge from hospital or up to a maximum period of 7 days. Daily review of the patient to assess time taken for mobility after surgery and to note any adverse events will be done. Upon discharge from hospital, the patients will be followed up via telephone interview to assess adverse events and mortality rates at 30 days. Mobility was assessed via Functional Independence Measure (FIM) motor domain which consists of a score from 13 to 91, with the higher score indicating better function.

Outcome measures include 30 day perioperative outcome, preoperative waiting time duration, time to mobilisation, mobilisation scores (FIM) at 30 days, and length of post-operative stay.

Statistical Analysis: A convenience sample of 40 patients were recruited for this pilot study to demonstrate feasibility. Continous data were expressed as Mean (SD) and categorical data as proportion (%) was reported. Student t test for analysis of continuous data and chi-suqared test for categorical data. Statistical analysis was performed using SPSS version 20.

CHAPTER 3: RESULTS

Table 4.1 Baseline demographics comparison between the subjects in the accelerated and standard group

Characteristics		**Accelerated** **n = 18**	**Standard** **n = 22**	***p*-value** [a]
Age, years (SD)		79.06 (9.37)	77.59 (10.08)	0.640
Gender, n (%)	Male	3 (16.7)	5 (22.7)	0.709[b]
	Female	15 (83.3)	17 (77.3)	
Comorbidities				
Hypertension, n (%)	Yes	11 (61.1)	12 (54.5)	0.755 [c]
	No	7 (38.9)	10 (44.5)	
Stable angina, n (%)	Yes	2 (11.1)	1 (4.5)	0.579 [b]
	No	16 (88.9)	21 (95.5)	
Previous PCI, n (%)	Yes	2 (11.1)	0	0.196 [b]
	No	16 (88.9)	22 (100)	
Diabetes, n (%)	Yes	7 (38.9)	6 (27.3)	0.509 [c]
	No	11 (61.1)	16 (72.7)	
Osteoporosis, n (%)	Yes	3 (16.7)	1 (4.5)	0.310 [b]
	No	15 (83.3)	21 (95.5)	
Stroke, n (%)	Yes	3 (16.7)	2 (9.1)	0.642 [b]
	No	15 (83.3)	20 (90.9)	
Epilepsy, n (%)	Yes	1 (8.3)	0	0.450 [b]
	No	17 (94.4)	22 (100)	
COPD, n (%)	Yes	1 (5.6)	1 (4.5)	1.00 [b]
	No	17 (94.4)	21 (95.5)	
Dementia, n (%)	Yes	4 (22.2)	4 (18.2)	1.00 [b]
	No	14 (77.8)	18 (81.8)	

[a] Student's T-test; [b] Fisher's Exact test; [c] Chi squared
SD = Standard deviation

A total of 40 patients were recruited for this study of which 18 patients were in the accelerated and 22 patients were in the standard group respectively. There was no significant difference between the age of the 2 groups (p=0.640). There was also no significant difference in the genders of the 2 groups (p=0.709) with majority of females in both group (83.3% vs 77.3%). Comorbidities were also analysed between the 2 groups in terms of presence of hypertension, stable angina, previous percutaneous coronary intervention (PCI), diabetes, osteoporosis, stroke, epilepsy, chronic obstructive pulmonary disease (COPD) and dementia. There were no statistical differences between the 2 groups for all comorbidities.

Table 4.2 Univariate analysis of the different duration variables between the subjects in the accelerated and standard group

Variables	**Duration**				**95% CI for mean difference**	***p*-value[a]**
	Accelerated n = 18		**Standard n = 20**			
	Mean	**SD**	**Mean**	**SD**		
Preoperative waiting time (hours)	5.44	1.42	51.05	38.97	-63.86 , -27.36	<0.001
Time to mobilisation (hours)	25.17	16.57	29.05 *	14.36	-14.22 , 6.45	0.450
Length of stay in hospital (days)	6.11	6.79	6.58 *	5.90	-4.71 , 3.77	0.824
Length of postoperative stay (days)	5.89	6.90	4.37 *	6.10	-2.82 , 5.86	0.482

[a] Student's T-test
* Analysis based on a sample of 19 subjects
SD = Standard deviation
CI = Confidence interval

Table 4.3 Univariate analysis of the 30 day FIM score between the subjects in the accelerated and standard group

Variables	Duration				95% CI for mean difference	*p*-value[a]
	Accelerated n = 15		Standard n = 17			
	Mean	SD	Mean	SD		
30 day FIM score	51.40	24.39	58.88	24.08	-25.00 , 10.04	0.390

[a] Student's T-test
SD = Standard deviation
CI = Confidence interval

Results of the preoperative waiting time, time to mobilisation, length of hospital stay and length of postoperative hospital stay between the subjects in the accelerated and standard group were tabulated in Table 2 while the results of the 30 day FIM score were tabulated in table 3. Univariate analysis (Student's T-test) was used to assess the differences. There was statistical significance between the preoperative waiting time of the 2 groups (5.44 hours vs 51.05 hours, $p<0.001$). For the other 3 measured variables, there were no statistically significant differences noted the 2 groups; time to mobilisation (25.17 hours vs 29.05, $p=0.450$), length of stay in hospital (6.11 days vs 6.58 days, $p=0.824$) and length of postoperative stay in hospital (5.89 days vs 4.37 days, $p=0.482$). There was also no significant difference between the 30 day FIM scores between the 2 groups (51.4 vs 58.88, $p=0.390$).

Table 4.4 Univariate analysis of the 30 day perioperative complications between the subjects in the accelerated and standard group

Variables		**Accelerated** **n = 18**	**Standard** **n = 21**	***p*-value** [a]
30 day perioperative complications, n (%)	Yes	3 (16.7)	3 (14.3)	1.000
	No	15 (83.3)	17 (85.7)	

[a] Fisher's Exact test

Both groups had 2 cases of death among its subjects. In addition to the deaths, 1 subject in the accelerated group was complicated with a surgical site infection while 1 subject had a periprosthetic hip fracture in the standard group. However, there was no significant differences in the 30-day perioperative complications rate between the 2 groups (16.7% vs 14.3%, p=1.000).

CHAPTER 4: DISCUSSION

Among the 22 patients randomised to standard care, there were two mortalities. The first was due to cardiac arrest secondary to acute pulmonary oedema which occurred on her third day of admission while waiting for surgery and another patient died due to acute coronary syndrome on postoperative day (POD) 1. Both were in-hospital deaths.

The accelerated group of 18 patients also had 2 deaths among them, however were detected during routine follow up at 30 days via telephone call. Both patients were mobilised post-operatively and discharged from hospital uneventfully on POD2 and POD3 respectively.

During the 30-day follow up one patient from the standard group experienced peri-prosthetic hip fracture due to a fall and required a second surgery. One patient from the accelerated group experienced a surgical site infection. When corrected for age, gender and co-morbidities, both groups had no statistical difference.

The outcome for both groups were not statistically significant. This could be due to the small sample size. The mean time to mobilisation in the accelerated group was slightly earlier at 51.40 hours (SD 24.39) hours versus 58.88 hours (SD 24.08). The mean pre-operative waiting time in the accelerated group was much earlier at 5.44 hours (SD 1.42) versus 51.05 hours (SD 38.97) revealing the length of time standard care patients had to wait if the surgery was not accelerated.

The length of post-operative stay in the accelerated group was longer (5.89 days, SD 6.9 vs 4.37 days, SD 6.1). The reason for this may be due to some patients who were discharged by the orthopedic team but were then either transferred to the geriatric unit for further optimisation and rehab or were kept in the wards longer due to logistics, financial difficulty to engage a care-taker or limited nursing care centres for postoperative recuperation. Hence the numbers may not reflect the actual time taken for patients to recover well enough for discharge.

The major limitation in this pilot study is due to the small sample size. The study was not powered to inform the clinical and the impact of accelerated hip surgery.

The small sample size was due to several challenges faced during patient recruitment. Surgical implants needed to be purchased by the family members prior to surgery and required payment in full shortly after the diagnosis of hip fracture was made. As a result, patients from lower socio-economic groups and pensioners with financial limitations, or family members who were travelling from afar to make the payment were unable to participate in the study. Due to the limited number of surgeons, only patients who were planned for open reduction and internal fixation were recruited and patients who required arthroplasty were not. Majority of patients presented after office hours and the lack of manpower to assess, randomise and operate during the night limited our sample study. The recruitment time was initially limited from 4am to 4pm. One of the reasons for this was because patients who required medical consultations, echocardiography or further investigations may prove difficult to arrange after working hours. The patients were screened by medical officers prior to recruitment and patients who were deemed high-risk, requiring consultant review or further stabilisation were not considered for the study. Patients who were recruited to the study and randomised to the accelerated group has their surgery expedited by opening additional operating theatres or slotted into emergency theatres.

As the study progressed, several measures were taken to improve recruitment rates. Recruitment time was increased to 24 hours and on-call doctors were made aware regarding the study. An operating theatre for orthopaedic cases was arranged to run at 24 hours instead of only during working hours. Implants were purchased in advance for the purpose of the study enabled patients with financial difficulty to participate. Regular interdisciplinary meetings were held to discuss the progress of the study and methods for improvement. With the above measures implemented, a total of 40 patients were

recruited. The strength of the study: We demonstrated the feasibility of the protocol with good protocol adherence. We also managed to follow-up all the patients at 30-day.

CHAPTER 6: CONCLUSION

Several studies have shown significant improvements in mortality rates in patients who have undergone early surgery for hip fracture in the elderly. It is postulated that early surgery reduces the exposure to harmful inflammatory, hypercoagulable and catabolic states which may have an impact on reducing vascular complications associated with surgery. Accelerating surgery in the elderly is subject to a multidisciplinary approach and timely intervention from the immediate presentation in the emergency department. The incidence of perioperative mortality, time to mobilisation, post operative length of stay and 30-day FIM scores did not show a significant difference in the 40 patients recruited for this pilot study. However, the feasibility of conducting the study has been very encouraging and can be realised on a larger scale.

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