Project Title

A Prospective, Randomized Controlled Trial Comparing the Use of the Proximal Femoral Nail – Antirotation and Dynamic Hip Screw for Stable Intertrochanteric Femur Fractures - Stable Trochanteric Fractures Intramedullary Versus Extramedullary (STRIVE) Study

Project Lead and Members

Project lead: Yeo Quan You

Project members: Mark Tan, Kaamini Pillay, Ivan Tjun Huat Chua, Ernest Beng Kee Kwek

Organisation(s) Involved

Department of Orthopaedic Surgery, Tan Tock Seng Hospital Singapore

Department of Orthopaedic Surgery, Woodlands Health Campus Singapore

Healthcare Family Group(s) Involved in this Project

Medical

Applicable Specialty or Discipline

Orthopaedic Surgery

Project Period

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Aims

Intertrochanteric (IT) hip fractures are the second most common fractures of the hip, associated with significant morbidity and mortality(1). The preferred management for this fracture is surgical intervention with the aim to restore the patient's premorbid function and avoid complications secondary to immobilisation. However,

there is little evidence guiding the optimal implant choice for fixation of stable Intertrochanteric (IT) fractures. The aim of this prospective study was to compare the PFNA II and the DHS in the treatment of stable IT fractures, specifically evaluating fracture reduction, functional scores, and complications.

Background

See poster appended/ below

Methods

See poster appended/ below

Results

See poster appended/ below

Lessons Learnt

This study found that the DHS performed as well as the PFNA for stable IT fractures in elderly patients. Both groups had similar intraoperative blood loss, surgical time and post-operative radiographic parameters. The DHS implant had non-inferior functional score (Parker Mobility Scores and Harris Hip Scores) compared with the PFNA. We recommend the use of the DHS for this fracture type in view of its cost savings and equivalent outcomes.

Conclusion

See poster appended/ below

Additional Information

Singapore Health & Biomedical Congress (SHBC) 2022: Singapore Clinician Investigator Award (Oral category) – (Bronze Award)

Project Category

Applied/ Translational Research

Quantitative Research

Keywords

Stable intertrochanteric hip fracture, Proximal Femoral Nail Anti-rotation (PFNA), Dynamic Hip Screw (DHS)

Name and Email of Project Contact Person(s)

Name: Yeo Quan You

Email: Quan_You_YEO@wh.com.sg

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Quan You YEO[1], Mark TAN[2], Kaamini PILLAY[2], Ivan Tjun Huat CHUA[2], Ernest Beng Kee KWEK[1]
[1]Department of Orthopaedic Surgery, Woodlands Health Campus, Singapore
[2]Department of Orthopaedic Surgery, Tan Tock Seng Hospital, Singapore

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INTRODUCTION

Intertrochanteric (IT) hip fractures are the second most common fractures of the hip, associated with significant morbidity and mortality. The index admission mortality for hip fractures was 5.7% and mortality at 1 year was 26%. Of those alive, 24% wheelchair bound and 9% bedridden.[1] However, there is little evidence guiding the optimal implant choice for fixation of stable Intertrochanteric (IT) fractures. Stable IT hip fractures were defined by the Muller AO Classification (31-A1.1, 31-A1.2, 31-A1.3 or 31-A2.1). The Dynamic Hip Screw (DHS), an extramedullary device, was introduced in the 1950s, and is still recognized as the standard device for fixation of intertrochanteric fractures due to its cost and reliability. The Proximal Femoral Nail Antirotation II (PFNA) is a recently developed intramedullary implant for treatment of intertrochanteric fractures. It is a load sharing device and has a shorter moment arm distance between the hip joint and implant. PFNA is inserted using minimally invasive technique and is postulated to lower the risk of soft tissue trauma, blood loss, infection and wound complications in unstable IT fractures.[2,3] Many studies has showed that PFNA have earlier mobilization and better functional recovery in unstable IT fractures.

Fig 1. Stable IT hip fracture

Fig 2. Dynamic Hip Screw (DHS)

Fig 3. Proximal Femoral Nail Antirotation II (PFNA)

RATIONALE

There is a paucity and mixed evidence guiding the optimal implant choice for fixation of stable IT fractures. Papers concluded that DHS had increase reoperation, longer surgical time and increase blood loss.[4] Hence, we conducted a prospective randomized controlled trial to provide evidence in terms of clinical, radiological and functional outcome in the treatment of stable IT fractures between the PFNA II and the DHS.

METHODOLOGY

This is a single blinded prospective, randomized controlled trial comparing the use of the Proximal Femoral Nail Antirotation II (PFNA) and the Dynamic Hip Screw (DHS) for the treatment of stable IT femur fractures in a single tertiary center (Tan Tock Seng Hospital, Singapore) with an established ortho-geriatric co-managed hip fracture care pathway between June 2014 and December 2018. All surgeries were conducted or supervised by a fellowship trained orthopaedic trauma surgeon. The patients were followed up for a period of 12 months with serial clinical and radiological evaluations. The study was conducted in accordance with CONSORT (Consolidation Standards of Reporting Trials) 2010 guidelines.

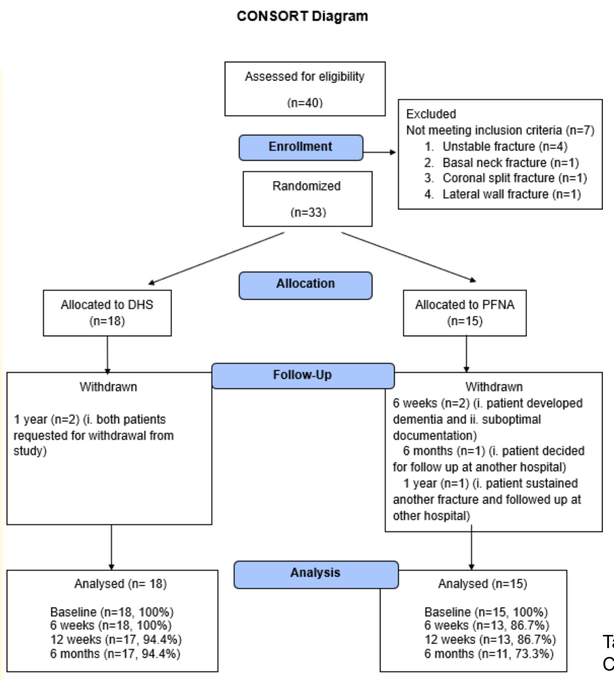
The primary objective was to compare the effectiveness of the PFNA with the conventional DHS in the treatment of stable intertrochanteric fractures with a view to Harris Hip Score as the primary endpoint.

The Secondary objectives were general complications, surgical details, fixation failure, radiological parameters, fracture union and functional scores.

Both groups underwent a standardized post-operative rehabilitation program that included standard surgical wound care, immediate full weight bearing ambulation and progressive strengthening exercises when the implant was noted to be stable based on radiological parameters

The patients were followed up for a period of 12 months with serial clinical and radiological evaluations at 6 weeks, 12 weeks, 6 months and 1-year intervals.

RESULTS



	DHS (n=18)	PFNA (n=15)	p value
Age	**Median (IQR[a])** 76.1 (72.3, 79.7)	**Median (IQR)** 70.9 (66.2, 78.7)	0.11
Gender	**N (%)**	**N (%)**	0.99
Male	8 (44.4)	6 (40.0)	
Female	10 (55.6)	9 (60.0)	
Ethnicity	**N (%)**	**N (%)**	0.99
Chinese	14 (77.8)	13 (86.7)	
Malay	2 (11.1)	2 (13.3)	
Indian	1 (5.6)	0 (0.0)	
Others	1 (5.6)	0 (0.0)	
BMI[b]	**Median (IQR)** 24.6 (20.0, 27.0)	**Median (IQR)** 23.3 (20.7, 26.3)	0.88
Smoking	**N (%)**	**N (%)**	0.99
Non-smoker	16 (88.9)	14 (93.3)	
Ex-smoker	1 (5.6)	1 (6.7)	
Smoker	1 (5.6)	0 (0.0)	
SF 36 [c]	**N (%)**	**N (%)**	0.94
Poor	0 (0.0)	0 (0.0)	
Fair	4 (23.5)	3 (21.4)	
Good	9 (52.9)	6 (42.9)	
Very Good	3 (17.7)	4 (28.6)	
Excellent	1 (5.9)	1 (7.1)	
Parker Mobility Score	**Median (IQR)** 9 (9,9)	**Median (IQR)** 9 (9,9)	0.75

Table 1. Comparison of Patient Demographic and Fracture Configuration between the DHS and the PFNA Groups.

	DHS (n=18)	PFNA (n=15)	p value
Type of Anaesthesia	**N (%)**	**N (%)**	0.99
General Anaesthesia	4 (22.2)	3 (20.0)	
Regional Anaesthesia	14 (77.8)	12 (80.0)	
Surgical Time (min)	**Median (IQR[a])** 47.5 (40, 60)	**Median (IQR)** 45 (45, 55)	0.70
Blood Loss (ml)	**N (%)**	**N (%)**	0.84
<50	9 (50)	9 (60)	
51-100	7 (38.9)	4 (26.7)	
101-150	1 (5.7)	0 (0.0)	
151-200	0 (0.0)	1 (6.7)	
201-250	1 (5.6)	1 (6.7)	
Intra-Operative Complication	**N (%)**	**N (%)**	-
Yes	0 (0.0)	0 (0.0)	
No	18 (100)	15 (100)	
Intra-Operative Transfusion	**N (%)**	**N (%)**	-
Yes	0 (0.0)	0 (0.0)	
No	18 (100)	15 (100)	
Post-Operative Blood Transfusion	**N (%)**	**N (%)**	0.13
Yes	3 (16.7)	7 (46.7)	
No	15 (83.3)	8 (53.3)	

Table 2. Comparison of Peri-Operative Findings between the DHS and the PFNA Groups.

	DHS (n=18)	PFNA (n=15)	p value
Days to Standing (with Aid)	**N (%)**	**N (%)**	0.99
1	13 (72.2)	12 (80.0)	
2	3 (16.7)	2 (13.3)	
3	2 (11.1)	1 (6.7)	
Days to Ambulation (with Aid)	**N (%)**	**N (%)**	0.21
1	8 (44.4)	6 (40.0)	
2	6 (33.3)	4 (26.7)	
3	4 (22.2)	1 (6.6)	
>3	0 (0.0)	4 (26.7)	
Harris Hip Score	**Median (IQR[a])**	**Median (IQR)**	
6 Weeks	75 (67, 77)	73 (67, 80)	0.90
3 Months	76 (73, 81)	75.5 (68.5, 82.5)	0.66
6 Months	79 (72.5, 88.5)	84 (75, 91)	0.69
12 Months	84 (78, 95)	80 (76, 88)	0.20
Parker Mobility Score	**Median (IQR)**	**Median (IQR)**	
6 Weeks	5 (2.5, 6)	4 (2, 7)	0.99
3 Months	6 (4, 6)	6 (4, 8)	0.68
6 Months	7 (5, 9)	9 (4, 9)	0.83
12 Months	7.5 (7, 9)	7 (5, 9)	0.28
Pain Score	**Median (IQR)**	**Median (IQR)**	
At Discharge	2 (2,2)	2 (1, 2)	0.09
6 Weeks	2 (0, 4)	0 (0, 1)	0.20
3 Months	0 (0, 2)	0 (0, 0)	0.68
6 Months	0 (0, 0)	0 (0, 2)	0.19
12 Months	0 (0, 0)	0 (0, 1)	0.23

Table 3. Comparison of Patient Post-Operative Functional Score between the DHS and the PFNA Groups.

	DHS (n=18)	PFNA (n=15)	p value
Medical Complication	**N (%)**	**N (%)**	0.99
Yes	1 (5.6)	1 (6.7)	
No	17 (94.4)	14 (93.3)	
Wound Complication	**N (%)**	**N (%)**	-
Yes	0 (0.0)	0 (0.0)	
No	18 (100)	15 (100)	
Revision Surgery	**N (%)**	**N (%)**	0.44
Yes	0 (0.0)	1 (9.1)	
No	14 (100)	10 (90.9)	
Tip Apex Distance	**N (%)**	**N (%)**	0.99
Acceptable	17 (94.4)	15 (100)	
Unacceptable	1 (5.6)	0 (18.2)	
Varus-Valgus Deformity	**N (%)**	**N (%)**	0.23
Present	3 (16.7)	0 (0.0)	
Absent	15 (83.3)	15 (100.0)	
Loss of Reduction	**N (%)**	**N (%)**	0.23
Present	3 (16.7)	0 (0.0)	
Absent	15 (83.3)	15 (100.0)	
Fracture Impaction	**N (%)**	**N (%)**	0.72
Present	8 (44.4)	5 (33.3)	
Absent	10 (55.6)	10 (66.7)	
Periprosthetic Fracture	**N (%)**	**N (%)**	-
Present	0 (0.0)	0 (0.0)	
Absent	18 (100)	15 (100)	
Blade Perforation	**N (%)**	**N (%)**	-
Present	0 (0.0)	0 (0.0)	
Absent	18 (100)	15 (100)	
Malposition of Implant	**N (%)**	**N (%)**	0.99
Present	1 (5.6)	1 (6.7)	
Absent	17 (94.4)	14 (93.3)	
Implant Loosening	**N (%)**	**N (%)**	-
Present	0 (0.0)	0 (0)	
Absent	18 (100)	15 (100)	
Implant Failure	**N (%)**	**N (%)**	0.46
Present	0 (0.0)	1 (6.7)	
Absent	18 (100)	14 (93.3)	

Table 4. Comparison of Post-Operative Clinical and Radiological parameters between the DHS and the PFNA Groups

DISCUSSION

The use of IM nail in the fixation of unstable IT fracture resulted in earlier mobilization and functional recovery in other studies.[5] These results however were not replicated in our study. We did not find any statistically significant difference between the 2 groups in terms of Harris Hip Score (HHS), Parker Mobility Score and pain score for the entire study period. In stable hip fractures, indirect reduction with traction table and minimal soft tissue dissection results in equivalent blood loss and postoperative pain. Furthermore, due to the inherent stability of these fracture patterns, the choice of implant becomes less relevant to its mechanical performance, and outcomes are more dependent on the ability to achieve a good reduction and stable construct with either implant.

Although studies showed that DHS has significantly longer operative time and higher blood loss, we found that in our study surgical time for the DHS group was 47.5 minutes compared to PFNA 45.0minutes and blood loss for 88.9% of the patients was less than 100ml compared to PFNA 86.7% even though tranexamic acid was not administered.[4] We attributed it to the stability of the fracture that required only indirect reduction and familiarity of the implants.

A short PFNA II implant costs USD$1220 compared to a 2-hole DHS at USD$490 in our institution. The cost difference is 250%. Cost analysis studies on the treatment of IT fracture also showed that the DHS implant is more cost effective for stable IT fractures after taking into account total inpatient cost, revision surgery and quality of life.[6]

The strengths of our study include the rigorous adherence to our prospective protocol. All patients were managed under an ortho-geriatric co-managed hip fracture care pathway and operations were conducted or supervised by a fellowship trained orthopaedic trauma consultant. We utilized 2 functional scoring systems that provides comprehensive assessment compared to other RCTs.

Our study limitations include small sample size and short duration of follow up. This could be due to higher proportion of our elderly hip fracture patients having dementia and poor premorbid ambulatory status. Severe osteoporosis in our population also resulted in fewer stable IT fracture.

CONCLUSION

In conclusion, our study found that the DHS performed as well as the PFNA for stable IT fractures in elderly patients. Both groups had similar intraoperative blood loss, surgical time and post-operative radiographic parameters. The DHS implant had non-inferior functional score (Parker Mobility Scores and Harris Hip Scores) compared with the PFNA. We recommend the use of the DHS for this fracture type in view of its cost savings and equivalent outcomes.

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