Journal of Research and Practice on the Musculoskeletal System JRPMS

Original Article

Is subvastus approach better in bilateral TKA? Comparison of early functional outcomes of subvastus and medial para-patellar approach in Simultaneous Bilateral Total Knee Arthroplasty (SBTKA)

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Abstract

Objectives: Medial para-patellar is common approach for TKA; Subvastus approach is technically demanding and spares the quadriceps mechanism. Does the subvastus approach significantly improve outcomes compared to medial para-patellar approach in simultaneous bilateral total knee arthroplasty (SBTKA)? **Methods**: The study conducted on 100 patients between Jan 2018 to June 2019 matched in base demographics and clinical parameters divided in two equal groups; medial para-patellar approach and subvastus approach. VAS and PROM assessed in early post-operative period. Functional outcomes assessed using WOMAC scores and KSS postoperatively up to 01 year. **Results**: VAS at 3rd week was significantly higher in para-patellar group. At 3 weeks, 6 weeks and 3 months follow-up WOMAC score was higher and KSS was lower in para-patellar group. At 06 months and 01 year both WOMAC and KSS scores were similar. Measured functional outcomes were consistently better in subvastus group. **Conclusion**: Subvastus approach had less post-operative pain, faster recovery and better functional outcomes after surgery as compared to medial para-patellar approach in early post-operative period. There was no difference in outcomes at 01 year. The complication rates, transfusion rate, hospital stay, requirement of physiotherapy and rehabilitation was similar for both groups. We conclude the subvastus approach significantly improves early outcomes in SBTKA cases.

Keywords: KSS, Medial para-patellar, Subvastus, TKA, PROM

Introduction

There are a number of surgical approaches described for TKA surgery[1], medial para-patellar approach is by far the most commonly practiced surgical approach due to its relative ease of joint exposure, less soft tissue retraction and easier dislocation of the knee prior to the bone cuts. In the medial para-patellar approach the quadriceps tendon is cut longitudinally which theoretically can greatly impact the function of the extensor mechanism of the knee postoperatively. Complications such as patellar fracture, subluxation as well as avascular necrosis of patella are also well known to occur as a direct consequence of this approach[2].

In 1929, Erkes described the subvastus approach to knee joint[3]; in 1991 the approach was popularized by Hoffman for use in TKA surgery specifically with the view to overcome some of the known disadvantages of a medial para-patellar approach. Central to the advocacy of the subvastus approach is the preservation of the quadriceps

The authors have no conflict of interest.

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Edited by: *Konstantinos Stathopoulos*

Accepted *29 March 2021*

mechanism, various studies in the literature suggest many other advantages like improvement in postoperative quadriceps muscle strength, improvement in patellar tracking, conservation of the patellar blood supply, expedited rehabilitation, and reduction in postoperative pain leading to shorter stay in hospitals[4], nevertheless the subvastus approach has a few disadvantages as well; the approach is technically difficult compared to the more popular medial para-patellar approach, has limitations in exposure of the knee joint, presents physical hindrance and poor visualization of the lateral compartment due to non-eversion of patella compared to the medial para-patellar approach. A significantly low rate of usage of the subvastus approach is mainly attributed to a steep learning curve and the technical skill required in using the approach for TKA surgery[5].

Post-operative pain, return to activities of daily life and the duration of recovery are primary concerns for the patients undergoing total knee arthroplasty (TKA)[6,7]. Post-operative recovery and return to function with medial para-patellar approach is well known to be protracted and painful as compared to the subvastus approach. Even if the final functional result is satisfactory it often falls short to meet the expectations of a large percentage of patients who undergo TKA in the early post-operative period especially with respect to the ease of rehabilitation. Cila E, Guzel V et al, observed that the subvastus approach provided more quadriceps strength in the early post-operative period (06 wks), but there was no significant difference when compared to the medial para-patellar approach at 03 and 06 months follow up[8]. Literature is scarce on the impact of surgical approach in TKA surgery and even rarer in bilateral TKA cases, various studies reported in literature comparing functional outcomes of both subvastus and medial para-patellar approaches present conflicting evidence[8-12]. Dutka J, Skowronek M et al reported that in the subvastus group patients had full active extension, and better KSS results, better range of motion at 12 days, 6 weeks, and 12 weeks as compared to the medial para-patellar group, they also reported the patients had less pain at 12 days post-operative. The subvastus approach thus provided patients better early clinical results, but both groups had comparable outcomes at longer follow-up[11]. Conflicting results were reported by Bourke MG, Jull GA et al in an RCT conducted comparing outcomes in medial para-patellar and subvastus approach, they reported that American Knee Society Scores (AKSS) or other outcomes though are comparable at the end of 18 months, the AKSS functional scores at 12 and 18 months favoured the medial para-patellar ($P<0.05$) approach; difficulty perceived by surgeons favoured the medial para-patellar ($P=.001$) as well as days to straight leg raise favoured the subvastus ($P=.044$) they concluded that the subvastus approach provides no clinical benefit after 12 months compared to the medial para-patellar approach[9].

There is a scarcity of high quality randomized controlled trials that compare early outcomes of both approaches and the better approach among the two remains uncertain in terms of surgeons learning curve, operation time, blood loss, post-operative pain, efficacy, complication rates, return to function and ease of rehabilitation to accurately assess the overall benefit of the subvastus approach compared to the medial para-patellar approach for TKA surgery. It is reasonable to assume that in SBTKA cases the cumulative impact on outcomes, advantages and disadvantages of each surgical approach will be in all probability more prominent compared to a unilateral TKA case. Aim of our study was to ascertain the impact on early outcomes of subvastus approach compared to medial para-patellar approach in SBTKA cases. The working hypothesis for the study being when a subvastus approach is used in SBTKA cases the accrued benefits of a quadriceps tendon sparing subvastus approach extrapolate and at the same time the known disadvantages related to cutting of the quadriceps tendon in the medial para-patellar approach too will be negated thereby having a significant cumulative impact on outcomes and recovery after surgery in SBTKA cases.

Methods

A prospective randomised interventional controlled double blind study was conducted at a large referral joint replacement centre on Military veterans and their spouses from January 2018 to June 2019. Institute ethical committee clearance certificate was obtained prior to the commencement of the study. The study was conducted on patients of osteoarthritis reporting to the Orthopaedics department undergoing SBTKA. **Inclusion Criteria**: Correctable varus/valgus deformity less than 20 degrees, quadriceps strength 5/5, bi-compartmental disease; **Exclusion Criteria**: Inflammatory arthritis, patients having previous distal femoral or proximal tibial osteotomies, bone defects (AORI Type 2 or more) in the tibial or femoral condyles , post-traumatic arthritis, extra-articular deformity, peripheral neuropathy, ligamentous laxity. Age more than 75 yrs, Body mass index (BMI) more than 30 kg/m^2, ASA Grade (American Society of Anaesthesiologists) more than ASA Grade II were included as exclusion criterion as per the existing policy of the centre for simultaneous bilateral TKA cases.

A total of 100 eligible patients which were matched in baseline demographics and clinical parameters were recruited for the study and randomly divided in two groups of 50 patients each; Group (A) medial para-patellar group and Group (B) subvastus group. There were 34 females and 16 males (n=50) in the para-patellar Group A and 32 females and 18 males (n=50) in the subvastus Group B. Mean age in para-patellar Group A was 61.92 yrs. (45-71) (n=50), the mean age in subvastus Group B was 63.12 (48-76) (n=50). Minimum sample size was estimated by using the study of Jung YB, Lee YS et al[13], which observed that postoperative range of motion of the knee by medial

para-patellar and modified subvastus was 87.3±10.9 and 99.2±13.0, respectively. Taking these values as reference, the minimum required sample size with 99% power of study and 5% level of significance was 38 patients in each study group. To reduce margin of error, total sample size taken was 100 (50 patients in each patient group). 50 patients in each group were allotted randomly for each approach. Randomization was done using research randomizer https://www.randomizer.org/. Set 1 was assigned to para-patellar (Group A) and set 2 to subvastus (Group B). Pre-operatively Knee radiographs (standing AP view, recumbent 30 degrees flexion lateral view and a skyline view) obtained as per the "*Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System*" guidelines.

All patients were explained in detail about the study and a written informed consent for participation in the study with an option to quit obtained from all the eligible patients included in the study, patients were blinded to the approach to be used in the surgery. All patients underwent a thorough pre-operative evaluation and detailed counselling about the procedure SBTKA and received pre-emptive analgesia (single dose of Tab etoricoxib 90 mg and Cap pregabalin 75 mg) the night before surgery as per the existing pre-operative preparation protocol of the centre.

All the patients underwent simultaneous bilateral total knee replacement (SBTKA) under spinal anaesthesia and both the knees were operated in same sitting using either the subvastus or medial parapatellar approach by single surgeon proficient in both the surgical approaches being routinely used in the centre.

Both the knees were operated in tandem after tourniquet inflation, subvastus approach was done using a 10 to 12 cm skin incision depending on the knee bulk, completely sparing the quadriceps tendon (Figure 1), incising the supra-patellar pouch and mobilising the quadriceps muscle keeping the vastus medialis muscle attachment intact.

Knee joint was exposed without eversion of the patella, and the surgery performed without dislocation of the knee joint (Figure 2).

Medial para patellar approach was done by the standard technique, skin incision was 10 to 12 cm long, capsule incised along the medial border of patella after leaving a 3 to 4mm cuff of the capsule attached to the patella, patella was everted and knee dislocated to perform the surgery.

All patients included in the study were implanted with posterior stabilised (PS) implants PFC Sigma PS (*De Puy Orthopaedics Inc., Warsaw, United States*). Tourniquet was used on both sides in tandem application, inflated prior to incision and deflated after the closure of skin incision. Surgical approach, tourniquet time and per-operative complications were registered. The patients included in the study were managed with the same postoperative protocol in terms of DVT prophylaxis (LMWH 5000 i.u. subcutaneous once a day started 6 hrs. after surgery up to day 05 post-operative followed by tab aspirin 325 mg twice a day up to 14th post-operative day), sequential compression device usage for 05 days postoperative and early mobilisation from bed and full weight bearing ambulation from next day morning. All patients received a adductor canal block (15 mL of 0.5% bupivacaine infiltrated around the saphenous nerves) in the anaesthesia suite post-surgery; Post-operative analgesia (PCM 650 mg infusion IV BD, tab etoricoxib 90 mg OD and inj tramadol 100 mg BD) up to 48 hrs. post-operative followed by tab PCM 1 gm 6 hrly, tab tramadol 100 mg 8 hrly, tab etoricoxib 90 mg, tab pregablin 75 mg orally up to day 05 post surgery; at discharge the patients continued with oral medication up to 03 weeks (by tab PCM 1 gm 8 hrly, tab tramadol 50 mg 12 hrly, tab etoricoxib 90 mg once a day, tab pregablin 75 OD orally. Preoperative antibiotics (Inj Cefperazone 2 gm IV + Inj gentamycin 80 mg IV) stat

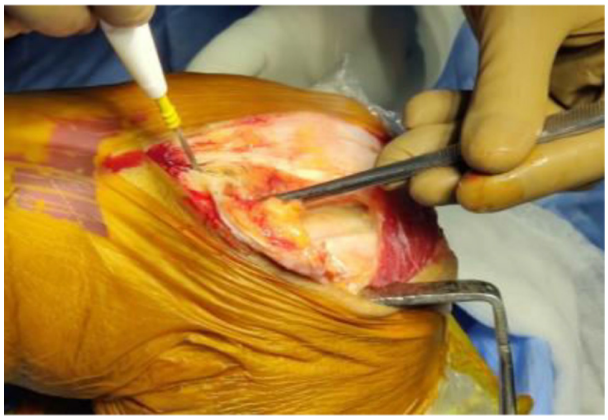

Figure 1. Extensor mechanism preserved in Subvastus approach.

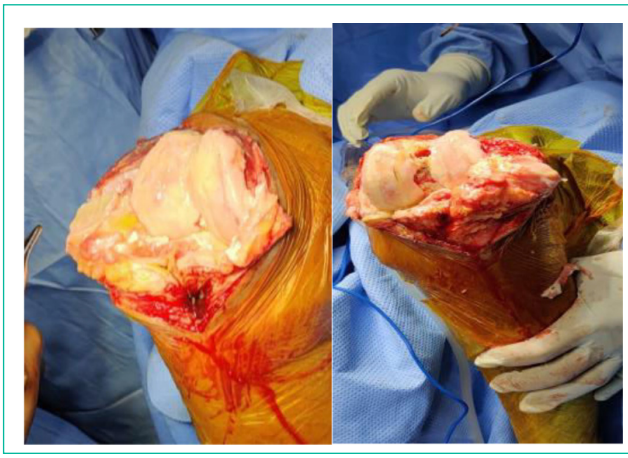

Figure 2. Restricted exposure of the lateral compartment in subvastus approach (A) compared to medial para-patellar approach (B).

Age distribution in years	Approach		Total	P value
	Group A Para patellar (n=50)	Group B Subvastus (n=50)		
<=50	4 (8.00%)	2 (4.00%)	6 (6.00%)	0.057
51-60	19 (38.00%)	16 (32.00%)	35 (35.00%)	
61-70	26 (52.00%)	23 (46.00%)	49 (49.00%)	
>70	1 (2.00%)	9 (18.00%)	10 (10.00%)	
Mean ± Stdev	61.92 ± 6.35	63.12 ± 7.14	62.52 ± 6.75	0.597
Median (IQR)	63.5(58 - 67)	62.5(58 - 68)	63(58 - 67)	

Table 1. Age distribution in the two groups.

Gender distribution	Approach		Total	P value
	Group A Para patellar (n=50)	Group B Subvastus (n=50)		
Female	34 (68.00%)	32 (64.00%)	66 (66.00%)	0.673
Male	16 (32.00%)	18 (36.00%)	34 (34.00%)	
Total	50 (100.00%)	50 (100.00%)	100 (100.00%)	

Table 2. Gender distribution in the two groups.

dose given 60 min prior to inflation of the tourniquet and a repeat dose afterwards if surgery time exceeded 2.5 hrs., post-operative antibiotics two doses (Inj Cefperazone 2 gm. IV) at 12 hrly interval; mobilisation, and full weight bearing ambulation with walking aid was started on day one. A wound check and de-bulking of the compression dressings was done at 5th post-operative day prior to discharge. Patients were discharged when they were ambulant with support of a walker, on oral pain relief medication and when at least 90 degree flexion was achieved, and provided standard discharge counselling as per protocol of the centre.

All patients included in the study were assessed for functional outcomes and radiographic evaluation done in the outpatient clinic by an independent observer blinded to the procedure at scheduled post-operative follow up visits at 03 weeks, 06 weeks, 03 months, 06 months and 01 year from the date of surgery as per the existing postoperative follow up protocol of our centre. VAS[14] was assessed on the 5th post-operative day and at 03 weeks post-operatively, PROM[15] were assessed at 03 weeks, 06 weeks and 03 months, WOMAC osteoarthritis index scoring, and Knee Society scoring system (KSS)[16] assessment was done at 03 weeks, 06 weeks, 03 months, 06 months and 01 year as per the study design to assess early outcomes. Radiographs obtained at the follow up visits in clinic at 06 weeks, 03 months, 06 months and 01 year as per the "*Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System*" and were evaluated using the Knee Society protocol for radiolucency at the bone-cement interfaces around the tibial and femoral components, any change in the position of the components, femoral-tibial alignment in the coronal plane, and osteolysis. Any collateral ligament laxity, subluxation of tibia, presence of osteophytes, any bone defects in the tibia and femur, and the quality of bone were also assessed. Staples were removed on the scheduled visit at 03 weeks in the clinic. No patient was lost to follow up.

Statistical Analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected, then nonparametric test was used.

Statistical tests were applied as follows:

Quantitative variables were compared using Independent t test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups and paired t test was used for comparison between pre and post. Qualitative variables were correlated using Chi-Square test/Fisher's Exact test. A p value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Occupation	Group A (Para patellar)	Group B (Subvastus)	P Value
None	1 (2.00%)	0 (0.00%)	0.215
Farmer	5 (10.00%)	1 (2.00%)	
Housewife	31 (62.00%)	31 (62.00%)	
Retired	13 (26.00%)	18 (36.00%)	
Height (in cm)			
Mean ± Stdev	156.54 ± 9.56	155.63 ± 9.96	0.631
Median(IQR)	157(148 - 163)	155(149 - 163)	
Weight(in kg)			
Mean ± Stdev	64.17 ± 8.95	66.03 ± 9.04	0.306
Median(IQR)	63.57(59.798 - 69.974)	64.99(59 - 72)	
Body mass index (kg/m²)			
Underweight	1 (2.00%)	0 (0.00%)	0.052
Normal	21 (42.00%)	11 (22.00%)	
Overweight	28 (56.00%)	39 (78.00%)	
Mean ± Stdev	26.21 ± 3.03	27.26 ± 2.36	0.114
Median (IQR)	26.42(23.936 - 29.200)	27.88(25.700 - 29.260)	
Quadriceps girth (in cm)			
Mean ± Stdev	37.41 ± 5.91	43.62 ± 16.73	0.063
Median(IQR)	37.35(35 - 42.300)	38.5(31 - 50)	
Tourniquet time (in minutes)			
Mean ± Stdev	39.66 ± 6.06	54.74 ± 17.59	0.0004
Median(IQR)	38.15(35.400 - 45)	53.5(40 - 60)	
Co-morbidities			
None	31 (62.00%)	41 (82.00%)	0.231
Benign prostatic hyperplasia	0 (0.00%)	1 (2.00%)	
Benign prostatic hyperplasia, transurethral resection of prostate	0 (0.00%)	1 (2.00%)	
Coronary artery disease	1 (2.00%)	0 (0.00%)	
Chronic obstructive pulmonary disease	1 (2.00%)	0 (0.00%)	
Diabetes mellitus	3 (6.00%)	2 (4.00%)	
Diabetes mellitus, hypothyroidism, hypertension	0 (0.00%)	1 (2.00%)	
Gilbert's syndrome	1 (2.00%)	0 (0.00%)	
Hypertension	9 (18.00%)	2 (4.00%)	
Hypothyroidism, hypertension	1 (2.00%)	0 (0.00%)	
Hypothyroidism	2 (4.00%)	2 (4.00%)	
VDRL positive	1 (2.00%)	0 (0.00%)	

Table 3. Comparison of baseline demographic and clinical parameters between the para-patellar and subvastus approach.

Results

Patients in Group A (para-patellar approach) and Group B (subvastus approach) were matched and had comparable median age (62.5 and 63.5; P=0.597) (Table 1) and comparable gender distribution (P=0.673) (Table 2). Uniform stratification in the type of occupation (P=0.215), height (P=0.631), weight (P=0.306), body mass index (P=0.114), quadriceps girth (P=0.063), and number of co-

VAS score	Group A Para patellar (n=50)		Group B Subvastus (n=50)		P value
	Mean ± St dev	Median (IQR)	Mean ± St dev	Median (IQR)	
VAS 5th day	6.58 ± 0.73	7(6 - 7)	6.22 ± 1.22	6(6 - 7)	0.22
VAS 3 weeks	5.6 ± 0.86	6(5 - 6)	4.22 ± 1.36	4(3 - 5)	<0001

Table 4. Comparison of VAS score between para-patellar and subvastus.

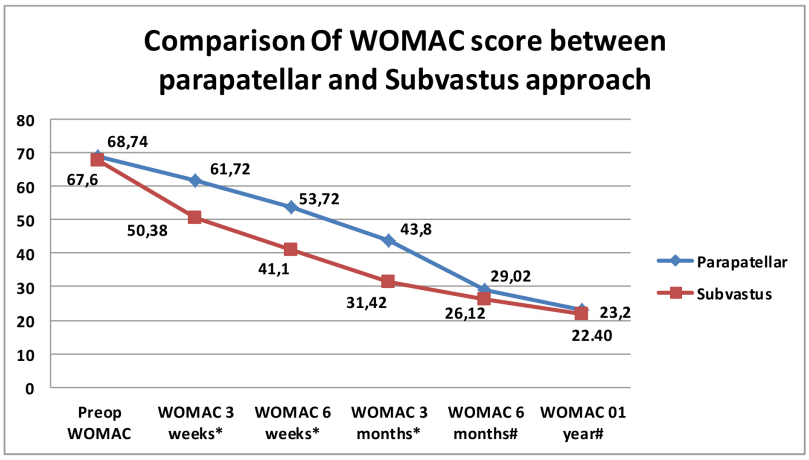

Figure 3. Comparison of WOMAC osteoarthritis indexes between Groups a (para-patellar) and Group B (subvastus) approaches. (*- p value<0.0001).

morbidities (P=0.231) was observed (Table3).

Median VAS score at 5th day was comparable in Group A para-patellar and Group B subvastus (7 & 6; P=0.22). Median VAS score at 3 weeks in Group A para-patellar approach was more than subvastus approach and statistically significant (6 & 4; P<.0001) (Table 4).

At 6 weeks, among the outcomes measures, compared to para-patellar Group A, subvastus Group B had significantly better health (P=0.049), significantly better mobility (P=0.008), significantly less postoperative pain (P=0.015), significantly less limping (P=0.019), significantly less night pain (P<.0001), significantly fared better in doing self-care (P=0.0002), significantly less problem in performing my usual activities (P=0.002), significantly less anxiety/depression (P=0.0001), and comparable results in knee suddenly give way or let down, usual daily activities affected, stair climbing, and requirement of physiotherapy (P>0.05).

At 3 months, among the outcomes measures, compared to para-patellar Group A , subvastus Group B had significantly better result (P=0.049), significantly less limping (P=0.039), significantly less night pain (P=0.018), significantly less felling of knee suddenly give way or let down (P=0.018), significantly better mobility (P=0.027), significantly better in doing self-care (P=0.012), significantly less problem in performing my usual activities (P=0.031), significantly less anxiety/depression (P=0.038), but comparable health, general status, postoperative pain, Usual daily activities affected, Stair climbing, and requirement of physiotherapy (P>0.05) (Table 5).

A uniform gradual reduction in WOMAC score was observed in both groups as compared to baseline pre-operative scores which were similar in the matched groups (68.74 in para-patellar group & 67.60 in subvastus group). In comparison to para-patellar group, reduction in WOMAC score in subvastus group was consistently more at 3 weeks (61.72 & 50.38; P<0.0001), 6 weeks (53.72 & 41.10; P<0.0001), and 3 months (43.80 & 31.42; P<0.0001) and was statistically significant (Figure3).

At 06 months follow up visit the WOMAC scores were convergent (29.02 & 26.12; P>0.05.) and statistically not significant by 01 year the WOMAC scores were similar (23.20 & 22.40; P>0.05) for both the groups and statistically not significant.

Significant uniform improvement in KSS score was observed in both groups up to 01year as compared to the

Table 5. Comparison of patients' health related questionnaire among the two groups.

Outcome measures		06 weeks		P value	3 months		P value
		Group A Para patellar (n=50)	Group B Subvastus (n=50)		Group A Para patellar (n=50)	Group B Subvastus (n=50)	
Health	Very good	6 (12.00%)	0 (0.00%)	0.049	2 (4.00%)	4 (8.00%)	0.218
	Good	7 (14.00%)	10 (20.00%)		40 (80.00%)	43 (86.00%)	
	Fair	35 (70.00%)	35 (70.00%)		8 (16.00%)	3 (6.00%)	
	Poor	2 (4.00%)	5 (10.00%)		0 (0.00%)	0 (0.00%)	
Result	Very good	0 (0.00%)	1 (2.00%)	0.659	6 (12.00%)	16 (32.00%)	0.049
	Good	13 (26.00%)	13 (26.00%)		36 (72.00%)	29 (58.00%)	
	Fair	27 (54.00%)	29 (58.00%)		8 (16.00%)	5 (10.00%)	
	Poor	10 (20.00%)	7 (14.00%)		0 (0.00%)	0 (0.00%)	
Comparison of general status	Better	0 (0.00%)	4 (8.00%)	<.0001	19 (38.00%)	24 (48.00%)	0.38
	About the same	40 (80.00%)	18 (36.00%)		23 (46.00%)	22 (44.00%)	
	A little worse	9 (18.00%)	20 (40.00%)		8 (16.00%)	4 (8.00%)	
	Much worse	1 (2.00%)	8 (16.00%)		0 (0.00%)	0 (0.00%)	
Post op pain	None	0 (0.00%)	0 (0.00%)	0.015	4 (8.00%)	4 (8.00%)	0.087
	Mild	7 (14.00%)	17 (34.00%)		31 (62.00%)	34 (68.00%)	
	Moderate	15 (30.00%)	18 (36.00%)		9 (18.00%)	12 (24.00%)	
	Severe	28 (56.00%)	15 (30.00%)		6 (12.00%)	0 (0.00%)	
Limping	Rarely/never	7 (14.00%)	7 (14.00%)	0.019	18 (36.00%)	27 (54.00%)	0.039
	Sometimes	7 (14.00%)	19 (38.00%)		25 (50.00%)	22 (44.00%)	
	Most of the time	36 (72.00%)	24 (48.00%)		7 (14.00%)	1 (2.00%)	
Night pain	No night pain	6 (12.00%)	1 (2.00%)	<.0001	15 (30.00%)	29 (58.00%)	0.018
	Some nights	16 (32.00%)	32 (64.00%)		29 (58.00%)	18 (36.00%)	
	Most nights	27 (54.00%)	9 (18.00%)		6 (12.00%)	3 (6.00%)	
	All nights	1 (2.00%)	8 (16.00%)		0 (0.00%)	0 (0.00%)	
Usual daily activities affected	Not at all	1 (2.00%)	1 (2.00%)	0.607	4 (8.00%)	6 (12.00%)	0.575
	Moderately	25 (50.00%)	21 (42.00%)		38 (76.00%)	39 (78.00%)	
	Greatly	23 (46.00%)	28 (56.00%)		8 (16.00%)	5 (10.00%)	
	Totally	1 (2.00%)	0 (0.00%)		0 (0.00%)	0 (0.00%)	
Knee suddenly give way or let down	Rarely/never	15 (30.00%)	25 (50.00%)	0.124	29 (58.00%)	41 (82.00%)	0.018
	Sometimes	32 (64.00%)	23 (46.00%)		9 (18.00%)	6 (12.00%)	
	Most of the time	3 (6.00%)	2 (4.00%)		12 (24.00%)	3 (6.00%)	
Stair climbing	Yes, easily	7 (14.00%)	10 (20.00%)	0.209	5 (10.00%)	4 (8.00%)	0.074
	With difficulty	24 (48.00%)	29 (58.00%)		38 (76.00%)	45 (90.00%)	
	With extreme difficulty	19 (38.00%)	11 (22.00%)		7 (14.00%)	1 (2.00%)	
Mobility	I have no problems in walking about	0 (0.00%)	7 (14.00%)	0.008	2 (4.00%)	3 (6.00%)	0.027
	I have some problems in walking about	30 (60.00%)	32 (64.00%)		38 (76.00%)	45 (90.00%)	
	I have great problem in walking about	20 (40.00%)	11 (22.00%)		11 (22.00%)	2 (4.00%)	
Self-care	I have no problems with self-care	1 (2.00%)	16 (32.00%)	0.0002	3 (6.00%)	13 (26.00%)	0.012
	I have some problems washing or dressing myself	47 (94.00%)	34 (68.00%)		47 (94.00%)	37 (74.00%)	
	I have severe problems washing or dressing myself	2 (4.00%)	0 (0.00%)		0 (0.00%)	0 (0.00%)	

Table 5. *(Cont. from previous page).*

Outcome measures		06 weeks		P value	3 months		P value
		Group A Para patellar (n=50)	Group B Subvastus (n=50)		Group A Para patellar (n=50)	Group B Subvastus (n=50)	
Usual activities	I have no problems with performing my usual activities	1 (2.00%)	12 (24.00%)	0.002	4 (8.00%)	13 (26.00%)	0.031
	I have some problems with performing my usual activities	47 (94.00%)	38 (76.00%)		46 (92.00%)	37 (74.00%)	
	I have severe problems with performing my usual activities	2 (4.00%)	0 (0.00%)		0 (0.00%)	0 (0.00%)	
Anxiety/ depression	I am not anxious or depressed	1 (2.00%)	17 (34.00%)	0.0001	4 (8.00%)	13 (26.00%)	0.038
	I am mildly anxious or depressed	48 (96.00%)	33 (66.00%)		45 (90.00%)	37 (74.00%)	
	I am moderately anxious or depressed	1 (2.00%)	0 (0.00%)		1 (2.00%)	0 (0.00%)	
Physio-therapy session	None	15 (30.00%)	15 (30.00%)	0.942	10 (20.00%)	10 (20.00%)	0.147
	1 to 5 times	13 (26.00%)	11 (22.00%)		3 (6.00%)	3 (6.00%)	
	6 to 10 times	2 (4.00%)	3 (6.00%)		0 (0.00%)	5 (10.00%)	
	More than 10 times	20 (40.00%)	21 (42.00%)		37 (74.00%)	32 (64.00%)	

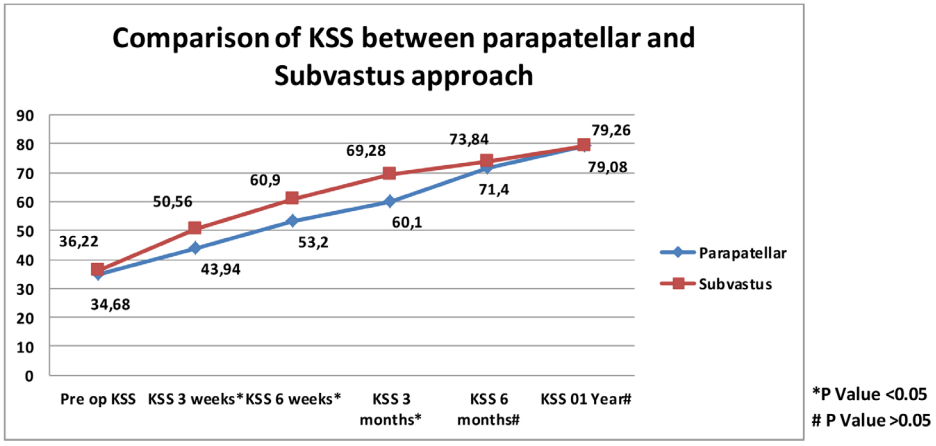

Figure 4. Comparison of KSS score between para-patellar and subvastus. (*- p value<0.0001).

baseline pre-operative scores which were similar in both the groups witch were matched (36.22 in subvastus group) and (34.68 in para-patellar group). However improvement in KSS score in subvastus Group B was more in comparison to para-patellar Group A at 3 weeks (50.56 & 43.94; <0.0001), 6 weeks (60.95 & 53.2; P<0.0001), and 3 months (69.28 & 60.1; P<0.0001) and was statistically highly significant (Figure 4).

At 06 months KSS scores for the subvastus approach were marginally better than the medial para-patellar approach (73.84 & 71.40; P>0.05) and at 01 year the KSS scores were similar (79.26 & 79.08; P>0.05) for both the groups and statistically not significant.

As compared to patients in Group A para-patellar approach, patients in Group B subvastus approach had significantly more tourniquet time (in minutes) (38.15 & 53.5; P=0.0004). Mean length of stay (LOS) was 5.4 days (4-7) in both Group A (n=50) & Group B (n=50).

Radiological evaluation at 01 year done using a weight bearing scanogram; there were no outliers in the mechanical

axis in both coronal and sagittal plane more than 02 degrees which is within the acceptable limits. No complications adversely affecting results were recorded in the groups, no haematoma formation, no infection, no perioperative fractures, no wound dehiscence, no case of delayed wound healing, no case of wound soakage, no return to OT, no revision in the follow up period up to 01 year. There was incidence of PE or DVT in the case series.

Discussion

Strategies to improve outcomes and patient satisfaction rates are a constant endeavour of any surgeon. Medial para-patellar approach is the most widely used approach in TKA surgery, in last two decades the subvastus approach has gained popularity has been advocated in literature citing advantages of the approach in better quadriceps function, faster rehabilitation and shortened recovery period compared to the standard medial para-patellar approach. Our study was modelled on the hypothesis that the cited advantages of greater quadriceps strength, less blood loss, and improved patellar tracking and less pain of subvastus approach done on both sides will complement each other in simultaneous bilateral TKA cases; additionally the complications specific to medial para-patellar approach due to violation of the quadriceps mechanism and disruption of the vascular supply of the patella such as subluxation and dislocation of patella, avascular necrosis of the patella, button loosening, and anterior knee pain, all of these likely to be higher in bilateral TKA cases too will reduce thereby significantly improving outcomes and overall patient satisfaction levels.

Jain S, Wasnik S et al conducted a RCT comparing outcomes in elderly obese patients undergoing simultaneous bilateral TKA using medial para-patellar and subvastus approach with no significant differences between both groups in terms of BMI, gender and age[17]. The mean age (76.1 yrs) in the study was high compared to our study. In our study the mean age was 62.52 yrs and comparable in both medial para-patellar and the subvastus group mean age (61.92±6.35 & 63.12±7.14, P=0.597) with comparable gender distribution (32.00% males & 36.00% males; P=0.673), comparable occupation, anthropometric parameters, and co-morbidities, this is certainly of importance in a prospective intervention trial as ours; comparability of the patient's demographic and clinical factors shows that any difference in outcome is purely due to the intervention and not due to chance bias[18]. In our study, the socio-demographic and pre-op characteristics of patients were statistically similar between the two treatment groups. Thus, the observed outcomes of the TKR can be ascribed to the two different surgical approaches used in the study.

We used VAS, KSS, WOMAC osteoarthritis index score and questionnaire proforma (Table 5) to assess functional outcome of the study. VAS is a simple, efficient, valid, and minimally intrusive method for measurement of post op pain; Disadvantage being more time consuming than other methods. Scott J, Huskisson EC et al in there study concluded that VAS horizontal or vertical scales have good correlation in pain assessment although horizontal scales tend to be lower than the vertical[20]. A potential drawback of VAS method is that the patient with higher or irregular intake of NSAID's for longer periods could have variable pain score and may result in bias in the results, hence we used the horizontal VAS scale generally used in clinical as well as home settings at 5th day and 03rd week post-surgery to assess postoperative pain as the pain protocol up to 03 weeks was similar for all patients included in the study. The patients received same pre-emptive analgesia and all patients included in the study underwent spinal anaesthesia for the surgery, received similar post op analgesia and were discharged on same oral pain relief up to 03 weeks post-operative, after the 03 week period the patients were advised oral NSAIDs on an as required basis; We found that the score was comparable pre-surgery; but after surgery no significant difference was seen in VAS scores at 5th day, while VAS scores at 3rd week was significantly lower in subvastus group as compared to para-patellar group (4.22±1.36 & 5.6±0.86, P<.0001). Amongst other studies, Jain S, Wasnik S et al found comparable VAS scores at day 0 (P=0.676), but significantly lower VAS scores with subvastus approach on day 1 and day 3 (P<0.05). However, both techniques showed comparable reduction in pain at discharge[17]. Even in study by Ugbeye ME, Ayodabo OJ et al there was significantly lower postoperative pain in the subvastus group versus the medial para-patellar group (2.8 versus 4.62 p<0.05)[21]. In another similar study by Bridgman SA, Walley G et al compared to baseline, pain score at the 01 year follow-up was significantly better in the subvastus group[22].

In our study KSS score was comparable pre-surgery; but after surgery, there was a significant increase of scores in both the groups as compared to baseline values (P<0.0001). Amongst the two approaches, KSS score at 3 weeks, 6 weeks, and 3 months was significantly lower in para-patellar approach (43.94±7.66, 53.2±8.04 and 60.1±6.53 respectively) as compared to that in subvastus approach (50.56±7.73, 60.9±8.22 and 69.28±7.15 respectively; P<.0001). At 06 months and at 01 year although the KSS scores for both groups improved and the scores for the subvastus approach were marginally better than the medial para-patellar approach (73.84 & 71.40; P>0.05.) and (79.26 & 79.08; P>0.05) and statistically not significant the increment of improvement of scores was more in the para-patellar group compared to the subvastus group. Similar results are reported in some other studies; Bridgman SA, Walley G et al, reported that in comparison with baseline, at one week follow-up, KSS scores were significantly better in the subvastus group[22]. Teng Y, Du W et al, reported that knee score was significantly better at 12 months in subvastus group[19]. Conflicting evidence was described in various other studies: Ugbeye ME, Ayodabo OJ et al (2018), reported that at 6 weeks, KSS did not show

any difference in outcome (p>0.05)[21], Berstock JR, Murray JR et al in a meta-analysis observed no difference in KSS at 6 weeks or 1 year in both surgical approaches (p>0.05)[4]. Koh IJ, Kim MW et al, reported that there was no significant difference between these two surgical approaches in terms of physician-assessed measures that included KSS score also[24].

At 3 and 6 weeks, post-operative Flexion deformity was significantly more in the para-patellar group than subvastus group (P<0.05) However, at 3 months, it was comparable among the two groups (P>0.05). Post-operative range of motion (ROM) was comparable at pre-op and at 3 weeks. At 6 weeks, it was more in the para-patellar group but at 3 months it was more in the subvastus group (P<0.05).

On WOMAC score we found that the score was comparable pre-surgery; but after surgery there was a significant decrease seen in both the groups as compared to baseline values (P<.0001). As compared to para-patellar approach WOMAC score was significantly lower in patients who underwent subvastus approach (P value <.05) although the scores declined uniformly for both groups. Between 03 months and 06 months the WOMAC scores declined steeply for the para-patellar approach and was similar to the subvastus approach at 06 months follow up visit (29.02 & 26.12; P>0.05.) by 01 year the scores were similar, our findings were in line with Bridgman SA, Walley G et al, where compared to baseline, WOMAC score at one year follow-up was significantly better in the subvastus group[22]. In a study by Koh IJ, Kim MW et al, there was no statistically significant difference between subvastus group and para-patellar group with respect to WOMAC score[24].

In our study design the patient reported outcome measures (PROM) were recorded at 06 weeks and 03 months follow up visit which we consider is optimal; by 06 weeks the patients recover well and regain health after a SBTKA surgery and cooperate in recording of PROM based on function and mobility removing any bias due to residual pain or intake of pain killers and by 03 months patients regain fully independent mobility and self-care. At 6 weeks post-op pain and limping were significantly less severe in subvastus group (p=0.015); whereas, at 3rd month, post-op pain was comparable (p=.087) and limping was significantly less in subvastus group (p=.039). Night pain, anxiety/depression, usual activities problems, mobility problems, and self-care problems were significantly less in subvastus group at 6 weeks and 03 months (P<0.05). No significant difference was seen on the effect on daily activities, stair climbing, and requirement of physiotherapy session in both groups (P>0.05). Experience of suddenly give way or let down of knee was similar at 6 weeks (p=0.124), but significantly less in subvastus group at 3 months (p=0.018). At 3 months the subvastus approach had significantly better results (p=0.049) while general status was comparable (p=.380) between the two approaches. Similar outcomes are reported by Berstock JR, Murray JR et al through a meta-analysis, they found superior results with subvastus approach in terms of time to regain an active straight leg raise as well as total range of knee movement at 1 week[4]. In another study by Koh IJ, Kim MW et al, patient-reported measures such as side preference and physician-assessed measures like range of motion and isokinetic muscle strength were comparable between subvastus group versus the medial para-patellar group (P>0.05) however in knees that underwent subvastus approach (SVA), there was greater quadriceps strength at postoperative 1 week as compared to medial para-patellar approach[24].

Many studies in the literature comparing the subvastus to the medial para-patellar approach report similar results however they are conducted on unilateral TKA cases and literature is sparse on the effect of surgical approach on SBTKA. Bridgman SA, Walley G et al reported that at one week follow-up, range of motion was significantly better in the subvastus group. SF36 physical function as well as role-physical scores, along with EuroQol utility and pain score, at the 1-year follow-up, were significantly better in the subvastus group. On comparing different parameters in both surgical approaches, the subvastus approach was more effective at both 1 week and 1 year postoperatively; however a less easy exposure was reported by surgeons in the subvastus group[22]. Peng X, Zhang X et al in 2015 reported that the subvastus approach had significant advantages over the standard para-patellar approach in ROM at postoperative 1 week and 12 months (P<0.05), straight leg raise, and lateral retinacula release, P=0.01). The two groups showed similar results in ROM at postoperative 4-6 weeks and 3 months, total complication rate, wound infection, and blood loss (P>0.05). Teng Y, Du W et al, reported that subvastus group showed similar results in range of motion, operative time, blood loss, hospital stay, and postoperative complications (P>.05)[19]. The subjective assessment of the patient well being showed significantly better results with subvastus approach in the follow up period although both approaches showed improvement.

Our study was limited in some aspects. Firstly, the follow up of the patients was carried out for a short duration. VAS and PROM long-term follow-up may be required to further explore the functional outcomes of the two surgical approaches. Secondly, some of the parameters such as total blood loss during surgery, surgery time and post-operative haematocrit assessment were not compared. An RCT on a large number of patients in future may provide insight into the quantum of impact of surgical approach in SBTKA cases.

Conclusion

Subvastus approach is technically demanding and has higher tourniquet time compared to the medial para-patellar approach. There is no difference in general health, transfusion rates, complications, LoS (Length of stay) in hospital or requirement of physiotherapy between the two approaches. In SBTKA cases subvastus approach has distinct advantages of reduced post- operative pain, faster recovery

from surgery and better functional outcomes compared to the medial para-patellar approach in the early post-operative period. However by 01 year the outcomes are similar in both the approaches. We recommend subvastus approach as the preferred approach in SBTKA cases.

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