International Journal of Healthcare Sciences ISSN 2348-5728 (Online)
Vol. 5, Issue 2, pp: (195-202), Month: October 2017 - March 2018, Available at: www.researchpublish.com

Efficacy of Patellar Denervation on Anterior Knee Pain and Knee Function Following Total Knee Arthroplasty: A Prospective Single-blind Clinical Trial

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***Abstract*: A prospective patient-blindclinical trial was carried in 20 candidates (patellar denervation in the right knee using circumferential cauterization, besides classical patelloplasty; and no denervation/patelloplasty to left knee) of simultaneous bilateral total knee arthroplasty (TKA) for end-stage osteoarthritis to assess the efficacy of patellar denervation in reducing anterior knee pain (AKP) following TKA. Presence, intensity and functional impact of AKP was compared between denervated (right) and non-denervated (left) knee using physical examination, visual analogous scale (VAS) and Kujala score, respectively; in addition to quadriceps diameter and sustained isometric exercise. Evolution over time of AKP was compared by 2-time assessment of pain intensity (< 1 year versus >1 year) using VAS. Eighteen patients completed the study. Prevalence (95%CI) of self-reported AKP was 22.2%; physical examination revealed that 61.1% patients had pain on patellofemoral compression; 16.7% had tender medial facet, and tender femoral grove each. No differences between denerveted and non-denerveted knees regarding pain intensity (VAS score=5.00±2.83 versus 5.11±2.72; p=0.317) or knee function (Kujala score=65.94±7.73 versus 67.17±11.60; p=0.346) were observed, respectively. Other assessments showed no difference in quadriceps diameter (p=0.375) or sustained isometric exercise (p=0.494). A significant decrease in pain was found over time in both denervated and non denervated knees, with no difference in change in pain intensity.This trial showed no efficacy of patellar denervation in reducing AKP following bilateral-TKA. Further trials are warranted to verify this result.**

***Keywords*: Anterior knee pain; total knee arthroplasty; knee replacement; patellar denervation.**

I. INTRODUCTION

Total knee arthroplasty (TKA) is vital in the management of advanced knee arthritis to restore knee function. Globally, the incidence of TKA is on rise. Statistics from the USA forecast a 673% increase in demand by 2030 [1] as life expectancy is increasing globally, and the elderly population wishes to maintain a good level physical activity. With over 49% of patients with osteoarthritis undergoingTKA, some authors are of the view that the demand will constantly increase as long as the procedure helps in reducing the debilitating pain and immobility associated with osteoarthritis[2]. TKA is an efficient and reliable treatment modality for advanced osteoarthritis as it not only improves the health related quality of life (QoL) but also alleviates the symptomatology. It is also associated with low mortality rates (0.4%), with unfavourable outcomes (post-operative pain) in 7-20% and with higher overall satisfaction (89%) among patients [1,3].

Anterior knee pain (AKP) is the most frequent complication of uncomplicated TKA reported in up to 49% of patients; but recent studies report a reduced average incidence between 8.0 -26.2%[4–7]. AKP is often non-disabling but may cause undue distress and low health related QoL, forcing patients to undergo revision in 1.9-7.8% of the cases [8]. Most publications indicate that AKP develops within the first 18 months and affects up to 49% of all patients who underwent

TKA within 5 years. Recent reports highlight the fact that AKP may occur as early as 6 months post-surgery. The aetiology and pathophysiology of AKP is still unknown. Various causes have been hypothesized with inflammation of bursae, tendons and synovium; as well as patella instability and fat pad entrapment and patterns of blood flow to the patella being considered to underlie the condition[5,9,10]. Currently, the most accepted aetiology is patellofemoral surface incongruence[6]. Advances have therefore been made to minimize the development of AKP; but given the multitude of factors, an appropriate management option remains elusive.

Multiple approaches such as resurfacing, lateral retinacular release, and mobile bearing implants have been explored to minimize AKP. In the recent times, resurfacing gained popularity due to reduced chances of reoperation after TKA. However, its utility remains controversial as it does not confer significant reduction of AKP[11,12]. Lateral retinacular release technique is recommended in intractable AKP post TKA and is based on the retinacular fibres being implicated to cause pain. However, its usefulness has been put to question after later publications revealed that nociceptive fibres are also present in the infrapatella fat pad as well as the medial retinaculum and therefore severing the lateral retinaculum only partially relives AKP[6,13]. Mobile bearing implants outcomes are relatively underexplored [14].

In the recent times, patella denervation is gradually becoming a preferred technique to manage post-TKA AKP. Patella denervation involves electro cauterization of the circumpatella tissues and desensitizes the anterior knee region[6]. Despite a high proportion of surgeons applying this technique, the outcomes of the procedure are considerably controversial. Earlier publications reported a reduction in knee pain with a concomitant improvement in knee function[14]. Some authors reported an improvement in the radiological outcomes. Subsequent randomized control trials, however, demonstrated contradictory results. This disparity was partially explained by the duration of post-TKA follow up significantly affecting the correlation between AKP occurrence and denervation[9,15]. Furthermore, it was reported that denervation only induces a considerable reduction in AKP in the first year, after which the benefit regarding knee pain declines considerably. Patella denervation wasalso incriminated in affecting cartilage integrity; which, in some cases, worsen knee pain and leadto reoperation. Some publications suggest that complementing patella denervation with another technique may give better outcomes[11]. It is however possible that the controversial results above may be partially explained by differences in knee rating systems or patient bias, in that some patients undergoing unilateral TKA may report AKP in its absence.

We therefore sought to assess the efficacy of patellar denervation in reducing AKP following simultaneous bilateral TKA.This trial attempted to study the efficacy of patellar denervation in reducing the incidence, intensity and functional impact of AKP following simultaneous bilateral TKA for end-stage osteoarthritis.

II. METHODOLOGY

This was a pilot prospective patient-blind clinical trial carried out at the department of orthopedics in King AbdulAziz University Hospital, Jeddah, Saudi Arabia. Patients with end-stage osteoarthritis who were candidate for primary simultaneous bilateral TKA were enrolled between September 2015 to December 2016. Patients undergoing multistage bilateral TKA or unilateral TKA, those with history of hip fracture, previous hip arthroplasty or tibiofemoral intervention, as well as rheumatoid arthritis were excluded. The study aim and protocol was explained for all patients and written consent was obtained prior to inclusion. The study protocol was ethically approved by the Institutional Review Board of King Abdulaziz University.

Procedure:

All patients underwent simultaneous bilateral TKA using the medial parapatellar approach[16,17],which corresponds to our routine practice.No knee underwent patellar resurfacing or lateral retinacular release. Osteophytes were removed where necessary. After implantation of the posterior cruciate-retaining primary prosthesis (Johnson & Johnson, Massachussetts, USA)with cement, circumpatellar electrocautery was performed on right knees (intervention group) using Conmed< electrocautery unit (Conmed Corperation, 2002, Mexico, Mexico). Electrocautery wasperformed to a depth of 2-3 mm and within 5 mmof the patella edge. Posterior-stabilized TKA system was performed using PFC (Sigma PS). All patients benefited from postoperative care including physiotherapy, antithrombotic prophylaxis and walking aids. No intraoperative or early postoperative complicationswere noted.

Outcome assessment:

Patients were assessed for pain and knee function, after at least 12 months follow up. The presence of AKP was assessed using patient-reported pain and physical examination including assessment of patellofemoral compression, tender medial facet compression, tender lateral facet compression and tender femoral grove compression of each knee, separately. Pain intensity was assessed using visual analogous scale (VAS), ranging from 0=no pain to 10=maximal imaginable pain. Knee function was assessed using the Kujalaknee score[18], which is a 13-item, validated questionnaire that assesses knee functional limitations and subjective symptoms during several situations, such as body weight support, walking, using stairs, running, etc. The Kujala score (0-100) is calculated as the sum of all item scores; and higher the score better the function. We also measuredquadriceps diameter (cm) and sustained isometric exercise (min.) as 2 other indicators of knee function. Each knee was assessed separately in all previous parameters including self-reported AKP, physical examination, VAS,Kujala, quadriceps diameter and sustained isometric exercise.Assessment was carried outduring follow up visit by 1 of the 2 surgeons who coauthored the study. In addition, patients were interrogated regarding daily average walking time (min. per day) and the use of analgesics. Data was collected on a coded excel sheet and processed in an anonymized manner.

Statistical Methods:

Statistical analysis was performed with the Statistical Package for Social Sciences version 21.0 for Windows (SPSS Inc., Chicago, IL, USA). Comparison of VAS and Kujala scores between right (denervated) and left (control) knees was carried out using Wilcoxon (nonparametric) test. Quadriceps diameter and sustained isometric exercise were compared using independent t-test, with the assumption that these 2 parameters are normally distributed. Presence of AKP and outcomes of physical examination were comparedusing chi-square test. Linear correlation was carried out to study the correlation of walking time with VAS score and Kujala score, separately for right and left knee. A p-value of <0.05 was considered to reject the null hypothesis.

III. RESULTS

Demographic and postoperative clinical characteristics:

Eighteen patients were included, 13 (72.2%) females; mean±SD [range] age=71.89±6.56 [61; 82] years. Mean±SD [range] time from bilateral TKA to assessment was 23.44±5.15 [12; 33] months. Self-reported AKP was found in 4/18 patients (prevalence [95%CI]= 22.2 [6.4; 47.6]%); unilateral in 2/4 cases (1 left and 1 right) and bilateral in 2/4 cases. Other postoperative assessments showed that 6/18 (33.3%) patients (those who have AKP + 2 others) reported having pain while climbing the stairs; 5/18 (27.8%) reported taking analgesics; and majority (15/18; 83.3%) reported having social activities. Mean±SD walking time was 37.50±14.06 minutes (range=15; 60minutes) (Table 1).

Table 1: Clinical characteristics of the population

Parameter	**Range**		**Mean/Freq.**	**SD/%**
	Min.	**Max.**		
AGE (years)	61.00	82.00	71.89	6.56
Gender				
Male			5	27.8
Female			13	72.2
Time from TKA to assessment (months)	12.00	33.00	23.44	5.15
Anterior knee pain (frequency, %)	**-**	**-**	**4**	**22.2**
Right	-	-	1	5.6
Left	-	-	1	5.6
Bilateral	-	-	2	11.1
Pain with stairs (frequency, %)	**-**	**-**	**6**	**33.3**
Up	-	-	3	16.7
Down	-	-	0	0
Both	-	-	3	16.7
Pain killer use **(frequency, %)**	-	-	5	27.8
Social activities **(frequency, %)**	-	-	15	83.3
Umrah (minor pilgrimage) frequency, %)				
No	-	-	14	77.8
Yes Walking	-	-	2	11.1
Yes Wheel-chair	-	-	2	11.1
Average walking time (min. per day)	15.00	60.00	37.50	14.06
Freq. Frequency; SD: standard deviation; %: percentage; VAS : visual analogous scale; prevalence [95%CI] of anterior knee pain = 22.2 [6.4; 47.6]%.				

Clinical assessment of anterior knee pain:

On physical examination, 11/18 (61.1%) patients had pain on patellofemoral compression (10 bilaterally and 1 unilaterally); 3/18 (16.7%) had tender medial facet (2 bilaterally and 1 unilaterally); and 3/18 (16.7%) had tender femoral grove (1 bilaterally and 2 unilaterally); while no patient had tender lateral facet (Table 2).

Table 2: Knee pain clinical assessment

Parameter	Category	Frequency	Percentage
Patellofemoral compression pain	Negative	7	38.9
	Unilateral	1	5.6
	Bilateral	10	55.5
Tender medial facet	Negative	15	83.3
	Unilateral	1	5.6
	Bilateral	2	11.1
Tender lateral facet	Negative	18	100.0
	Unilateral	0	0.0
	Bilateral	0	0.0
Tender femoral grove	Negative	15	83.3
	Unilateral	2	11.1
	Bilateral	1	5.6
Table presents results of pain clinical assessment using different physical examination methods. Results show no unilaterality of pain, which suggests no difference in clinically-induced pain between right and left knees.			

Effect of patellar denervation on anterior knee pain and knee function:

Comparison between right (denervated) and left (non-denervated) knees showed no difference regarding pain (mean±SD VAS score=5.00±2.83 versus 5.11±2.72; p=0.317 [Wilcoxon test]) or knee function (mean±SD Kujala score=65.94±7.73 versus 67.17±11.60; p=0.346 [Wilcoxon test]), respectively. No statistically significant difference was observed in any of the Kujala items as analyzed separately. Other assessments showed no difference in quadriceps diameter (p=0.375) or sustained isometric exercise (p=0.494) between denervated and non-denervated knees (Table 3).

Table 3: Assessing patellar denervation outcomes by comparison to standard surgical method (right versus left knee outcomes)

Parameter	Right knee		Left knee		Statistics	p-value
	Mean	SD	Mean	SD		
Quadriceps diameter (cm)	50.58	7.69	50.17	8.46	0.910[t]	0.375
Sustained isometric exercise (min)	42.50	4.42	42.00	5.51	0.699[t]	0.494
VAS pain (score)	5.00	2.83	5.11	2.72	1.000	0.317
KUJALA 1 (limp)	4.44	0.92	4.11	1.02	-1.732	0.083
KUJALA 2 (support)	4.56	0.86	4.33	0.97	-1.414	0.157
KUJALA 3 (walking)	2.06	1.21	2.44	2.23	-1.000	0.317
KUJALA 4 (stairs)	7.78	2.56	7.22	3.52	-0.707	0.480
KUJALA 5 (squatting)	0.00	0.00	0.00	0.00	0.000	1.000
KUJALA 6 (running)	0.00	0.00	0.72	2.42	-1.342	0.180
KUJALA 7 (jumping)	0.00	0.00	1.22	3.23	-1.633	0.102
KUJALA 8 (prolonged sitting with knee flexed)	8.78	1.56	9.00	1.57	-0.707	0.480
KUJALA 9 (pain)	9.11	1.02	9.00	1.24	-0.447	0.655
KUJALA 10 (swelling)	9.89	0.47	10.00	0.00	-1.000	0.317
KUJALA 11 (abnormal painful kneecap movements)	9.44	1.65	9.33	1.94	-0.447	0.655
KUJALA 12 (thigh atrophy)	4.89	0.47	4.78	0.65	-1.000	0.317
KUJALA 13 (flexion deficiency)	5.00	0.00	5.00	0.00	0.000	1.000
KUJALA score	**65.94**	**7.73**	**67.17**	**11.60**	**-0.943**	**0.346**
KUJALA short score[1]	42.11	3.77	42.11	4.76	-0.424	**0**.671
Unless otherwise specified, statistics and p-values are calculated using Wilcoxon test (nonparametric); [t] t-statistics (paired t-test); [1]Short score includes pain-related questions (question 8-12); statistical significance is fixed for a p-value<0.05.						

Effect of pain and knee function on physical activity:

Walking time (in minutes) was analyzed as an indicator for physical activity, and was correlated with each knee pain (VAS score) and function (Kujala score). Results showed a moderate negative correlation of walking time with pain, with no difference in correlation coefficients between right (r=0.503; p=0.033) and left knees (r=0.515; p=0.029) (Fig. 1). On the other hand, a strong positive correlation was found between walking time and right knee Kujala score (r=0.716; p=0.001); whereas a moderate correlation was found with left knee Kujala score (r=0.654; p=0.003) (Fig. 2).

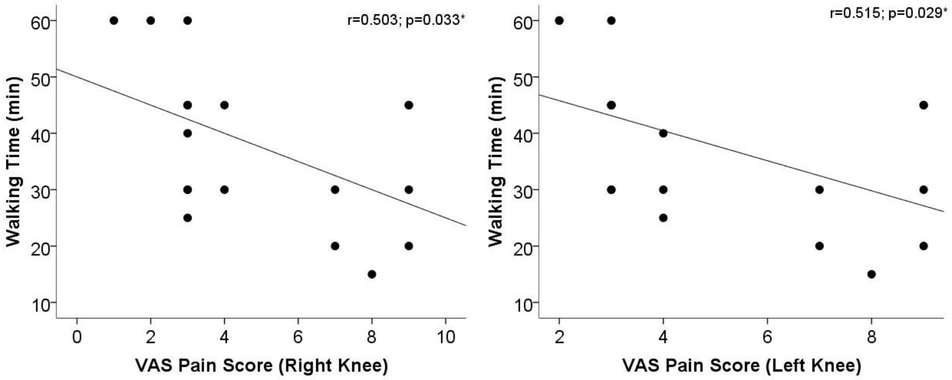

Figure 1. VAS x Walking time UPDT

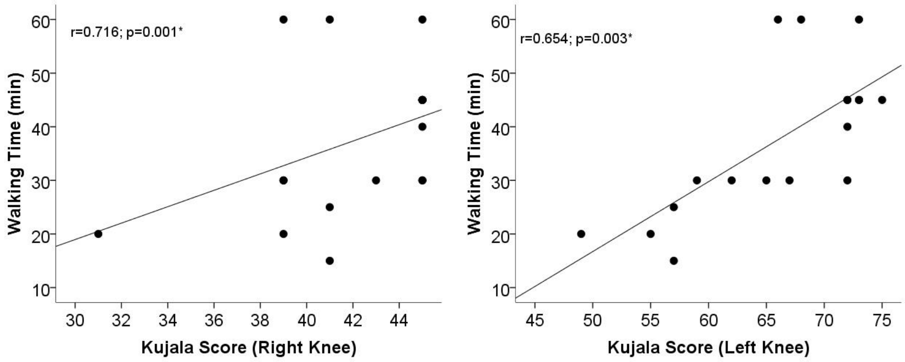

Figure 2. Kujala x Walking time 2

Evolution over time of anterior knee pain:

In 10/18 patients, self-reported pain (VAS) was assessed in early postoperative time (mean±SD [range] time from procedure to assessment=7.80±2.35 [4; 12] months). Evolution over time of the pain was assessed in both knees using paired nonparametric analysis. Results found significant decrease in pain in both right (statistics=4.500; Wilcoxon signed-rank test; p=0.031) and left knee (statistics=5.500; Wilcoxon signed-rank test; p=0.043) (Fig. 3). Comparison of change in pain intensity (Δ VAS) between right and left knee showed no statistical difference (statistics=21.500; Wilcoxon signed-rank test; p=0.615).

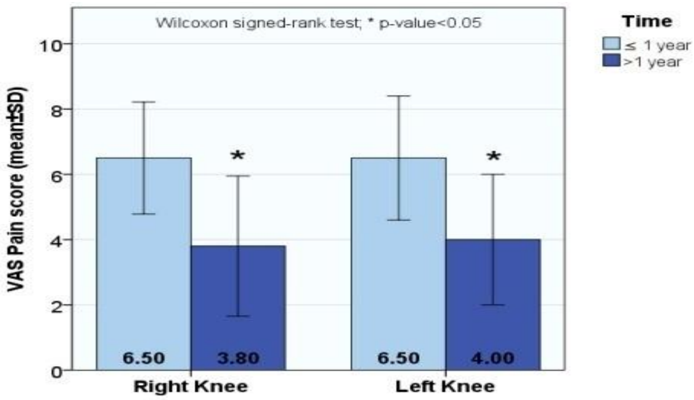

Figure 3. Time evolution of pain

IV. DISCUSSION

The current study explored the effect of patella denervation in 18 patients who underwent bilateral TKA for advanced knee osteoarthritis. Pain , knee function scores and the evolution of pain post-TKA was studied.

Four patients (22.2%) developed AKP, 6 patients (33.3%) reported AKP on exertion when climbing a fleet of stairs. Five patients experienced considerable AKPand used analgesics. Most patients (83.3%) still undertook their social activities e.g. walking for an average of 37.5 minutes without complaints. On clinical examination, the bilateral pain was elicited on patellofemoral compression in 10 patients (55.5%). This was higher than the observed incidence of self-reported pain in our study population. Medial facet and femoral groove pain were present in 3 patients each while there was no case of lateral facet pain. Further, patients who experienced bilateral AKP, did not report any statistically significant difference in the pain scores between denervated and non-denervated knees. There was also no difference in quadriceps diameter and sustained exercise between denervated and non-denervated knees. We observed a moderate correlation between pain, knee function, and AKP. However, no difference was reported in the correlations between the denervated and non-denervated knees. In this study, we demonstrated AKP as early as 8 months post-TKA. Even though the denervated knees had lower pain scores, no significant and demonstrable difference were observed between the denervated and nondenervated limbs.

The incidence of AKP has previously shown great variance. It has previously been reported that AKP may occur in as low as 4% and up to 49% of all patients who have undergone TKA [6,19]. This great variation is attributable to multiple factors such as the type of prosthesis and friendliness to the patella as well as the alignment of the extensor mechanism post-TKA [19]. In our study, we report an incidence of 22.2%. This is relatively low compared to literature and similar to the incidence reported by Metsna et al., who reported 20.2% cases of AKP among 1778 consecutive TKAs without patellar replacement [5]. Relatively lower incidence in our study isin favor of the general trend towards lower incidences in the recent past. The reduction in incidence in recent years may be attributed to improvements in minimizing AKP by various methods such as resurfacing, denervation or lateral retinaculum release[19–21].

Patella denervation has been reported to reduce AKP in previous reports. In our study, there was a slight reduction in AKP in the denervated group but the difference between the denervated and the non-denervated group did not meet statistical significance. Reports of patella denervation having a disputable role in reducing knee pain exist [9],with Boerger et al. having previously indicated the controversy surrounding denervation; in that denervation does not probably reduce AKP when compared to other techniques[16]. Sadigursky et al.,(2017) highlighted the fact that the studies demonstrating reduction of AKP after denervation report reduction in knee pain only in the first year post-TKA; while other studies report only an improvement in knee function scores without alleviation of knee pain [16]. The finding, denervation did not significantly alter the pain scores in our study raises more questions on its role in preventing knee pain. Different surgical approaches have a significant role in the latter and studies ought to compare outcomes based on the surgical approach. Moreover, pain remains to be a subjective symptom and its evaluation is not standardized across the studies[21].

The mechanism of alleviation of AKP in patella denervation is based on the pattern of innervation ofthe soft tissues around the knee. Branches of the lateral femoral cutaneous, anterior cutaneous branch of the femoral nerve and the medial femoral cutaneous nerves are the main neural twigs to the knee region. With exception of the cartilages, the rest of the knee tissues are innervated; and this nerve supply is thought to predispose patients to AKP. Denervation by electrocauteryessentially desensitizes the anterior knee region[11].

This study demonstrated that AKP decreases over time regardless of whether patellar denervation was performed. It was previously reported that preoperative pain intensity decreases 50% after 3 monthspost-TKA; but a slower decrease is observed later, until maintaining a residual intensity [22,23].

Results of this study have been limited by small sample size not allowing adjusting analysis for known risk factors such as preoperative pain and osteoarthritis severity, which may differ between the 2 kneesin the same patient [24–26]. The fact that the clinical assessors were privy to the treatment of the patients i.e. a knee was denervated and the other was non-denervated may have also biased the assessment. Further, itmay be difficult for patients to discriminate between right and left knee in functional assessment by Kujala score, as all functions involve both knees' integrity.

We recommend that double-blind randomized trials should be carried out, as well as meta-analyses that stratify all cases based on surgical approach as well as scoring systems.

V. CONCLUSION

This pilot study showed no superiority of patellar denervation over standard surgery in controlling AKP following simultaneous bilateral TKA. This resulted in identical functional outcomes including walking time and mechanical pain suggesting absence of benefit in QoL. Furthermore, it demonstrated a moderate to strong negative correlation of walking time with both VAS and Kujala score.Further double-blind clinical trialswith appropriate sample size and risk-adjusted analysis are required to confirm or reject the results from this pilot study.

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