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A 5 year prospective double blind comparative study of ACL reconstruction using hamstring single bundle vs double bundle graft

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Abstract

Introduction: Over the last few decades injuries of the knee joint have played a major role, due to many popular knee pivoting sports including soccer, skiing and basketball.

Ligament injury accounts for nearly 40% of all knee injury problems and isolated anterior cruciate ligament injury constitutes nearly 50% of all knee ligament injuries. Approximately 3,00,000 anterior cruciate ligament reconstructions are performed in the USA alone each year. Better understanding of injury mechanisms lead to prevention strategies against anterior cruciate ligament injury with some effectiveness although, anterior cruciate ligament injury is still not fully preventable.

Anterior cruciate ligament was considered of little importance for the long term function of the knee in the past. Studies have shown that there is greater risk of meniscal and articular injuries in short term progressing to radiological and clinical changes of joint degeneration in the long term in anterior cruciate ligament deficient patients compared to subjects with normal anterior cruciate ligament function.

Non operative management has not been proven to prevent or delay long term sequelae of anterior cruciate ligament deficiency. Early surgical methods such as primary repair of anterior cruciate ligament injury with or without augmentation showed a modest to poor improvement over non-operative management in terms of subjective and functional outcome of symptomatic knee instability.

Reconstruction of ACL is best way of management with failure rate of around 10 %. Varieties of graft materials available for surgeons' choice are auto grafts, allograft and synthetic graft materials. Success rates of ligament reconstruction using auto grafts are higher than when either allograft or synthetic graft materials were used. Anterior cruciate ligament reconstruction is done either by single bundle or double bundle reconstruction. Double bundle reconstruction is increasingly common. However, no definitive data on the superiority of double bundle technique have been shown when compared with single bundle reconstruction.

In the present study we have tried to compare outcome of single bundle and double bundle Anterior cruciate ligament Reconstructions using semitendinosus tendon tripled with ipsilateral and contralateral Semitendinosus tendons for double bundle technique and only ipsilateral Semitendinosus tendon for single bundle technique with tunnel mouth fixation of graft using smooth threaded interference screws (UNILINK, Mumbai) in all the cases in both groups.

Aim of the study: To objectively evaluate short term functional results of single bundle (non-isometric) and double bundle (single tibial tunnel with two femoral tunnels – 11 0' clock & 9.30 or 1 0' clock & 2.30 positions) arthroscopic anterior cruciate ligament reconstruction using semitendinosus tendon (autologous) and tunnel mouth fixation.

Conclusion: we conclude No clear cut advantage for either Single bundle technique or Double bundle technique of anterior cruciate ligament reconstruction in terms of post-operative outcomes or complications.

Keywords: ACL, Hamstring graft, single bundle graft, double bundle graft

Introduction

Over the last few decades injuries of the knee joint have played a major role, due to many popular knee pivoting sports including soccer, skiing and basketball^[1].

Ligament injury accounts for nearly 40% of all knee injury problems and isolated anterior cruciate ligament injury constitutes nearly 50% of all knee ligament injuries^[2-4].

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Approximately 3,00,000 anterior cruciate ligament reconstructions are performed in the USA alone each year [5]. Better understanding of injury mechanisms lead to prevention strategies against anterior cruciate ligament injury [6] with some effectiveness although, anterior cruciate ligament injury is still not fully preventable.

Anterior cruciate ligament was considered of little importance for the long term function of the knee in the past [7]. Studies have shown that there is greater risk of meniscal and articular injuries in short term progressing to radiological and clinical changes of joint degeneration in the long term in anterior cruciate ligament deficient patients compared to subjects with normal anterior cruciate ligament function [8-12].

Non operative management has not been proven to prevent or delay long term sequelae of anterior cruciate ligament deficiency [13]. Early surgical methods such as primary repair of anterior cruciate ligament injury with or without augmentation [14] showed a modest to poor improvement over non-operative management in terms of subjective and functional outcome of symptomatic knee instability [15].

Reconstruction of acl is best way of management with failure rate of around 10% [16]. Varieties of graft materials available for surgeons' choice are autografts, allograft and synthetic graft materials. Success rates of ligament reconstruction using autografts are higher than when either allograft or synthetic graft materials were used. Anterior cruciate ligament reconstruction is done either by single bundle or double bundle reconstruction. Double bundle reconstruction is increasingly common. However, no definitive data on the superiority of double bundle technique have been shown when compared with single bundle reconstruction.

In the present study we have tried to compare outcome of single bundle and double bundle Anterior cruciate ligament Reconstructions using semitendinosus tendon tripled with ipsilateral and contralateral Semitendinosus tendons for double bundle technique and only ipsilateral Semitendinosus tendon for single bundle technique with tunnel mouth fixation of graft using smooth threaded interference screws (UNILINK, Mumbai) in all the cases in both groups.

Aim of the study: To objectively evaluate short term functional results of single bundle (non-isometric) and double bundle (single tibial tunnel with two femoral tunnels – 11 O' clock & 9.30 or 1 O' clock & 2.30 positions) arthroscopic anterior cruciate ligament reconstruction using semitendinosus tendon (autologous) and tunnel mouth fixation.

Materials and Methods

This is a prospective randomized double blind study of sixty five patients presenting with chief complaint of the knee instability and/or pain presenting to Balaji Institute of Surgery, Research and Rehabilitation for the Disabled hospital from year April 2012 to March 2013 were diagnosed clinically by Lachman test, anterior drawer test, pivot shift test under anaesthesia and confirmed by diagnostic arthroscopy to have anterior cruciate ligament tear. These patients were treated with anterior cruciate ligament reconstruction using autologous ipsilateral semitendinosus for Single bundle technique and ipsilateral and contralateral semitendinosus grafts for Double bundle technique and followed up for 5 years. Out of 65, 5 patients lost follow up. Post-operative evaluation was done based on international knee documentation committee subjective assessment score, Tegners' score, Lysholm scores and international knee

documentation committee objective evaluation and postoperative complications.

Inclusion criteria

1. Age of patients ranging from 17 to 40 years.
2. Anterior cruciate ligament tear that occurred more than 4 weeks.
3. No previous surgery performed on the affected knee.
4. No previous cruciate ligament damage sustained in either the affected or the contralateral knee.

Exclusion criteria

1. Patients with medial collateral ligament laxity.
2. Patients with lateral collateral ligament laxity.
3. Patients with posterior cruciate ligament laxity.
4. Evidence of osteoarthritis on plain radiographs.
5. Patients with associated mesniscal tears.

All patients were enrolled to undergo primary arthroscopically assisted anterior cruciate ligament reconstruction and randomized into a Single bundle or Double bundle groups using closed envelopes by independent person. The study was approved by the local ethical committee and the patients gave their informed consent to participate.

Surgical steps anterior cruciate ligament reconstruction with Single bundle method

Graft harvestation

A 3cms medial skin incision was made midway between tibial tuberosity and medial most aspect of upper tibia. The tendons were palpated and the sartorius fascia was incised parallel to the fibers of the fascia just above the thicker and more distally inserted hamstring tendons. After the vinculae had been cut under visual control, the distal end of tendon was cut and graft was harvested with a semiblunt, circular closed tendon stripper.

Graft preparation

The tendon was prepared for quadruple graft, depending on the length of the tendon. The minimum accepted length for the final graft was 7 cm. No.2 Ethibond suture was used for preparation of proximal and distal ends of the graft by whip stitch method. Two No. 5 non-absorbable Ethibond sutures were used as the lead sutures at the distal and proximal ends.



Fig 1: Graft Preparation

Tunnel preparation

After arthroscopic examination of knee joint was done and tibial tunnel was prepared by placing zig. Through an accessory anteromedial portal guide wire was placed in 10 'o clock position over lateral femoral condyle inner aspect 2mm from posterior most corner of cortex and femoral tunnel drilled with knee in 100 to 110 degrees of flexion.

Graft placement and fixation

Through tibial tunnel graft was placed in position and secured with soft threaded interference screw on femoral side. After the femoral screw had been inserted, firm traction was applied

to the graft, tibial screw was inserted posterior to the graft, with knee in 90 degrees of flexion. Knee was examined for laxity. Wound closed in layers and compression bandage was applied.

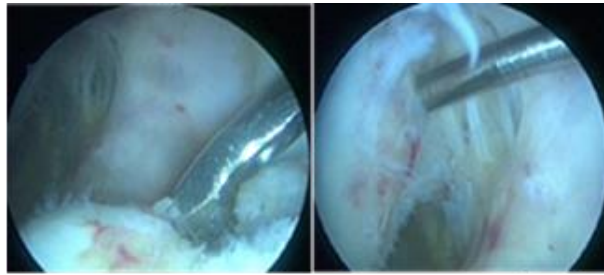


Fig 2: Tunnel Preparation

Surgical steps of anterior cruciate ligament reconstruction with Double bundle method graft harvesting similar to single bundle in addition semitendinosus tendon was harvested from opposite leg. Little variation in graft preparation the harvested Semitendinosus tendons were prepared for quadruple graft separately with one graft measuring 9cm and other measuring

8cm length for anteromedial and posterolateral bundles respectively. Both grafts sutured at one end in Y- shape showed in picture below. No. 2 ethibond suture was used for preparation of the graft by whip stitch method. Three no.5 ethibond sutures were used as the lead sutures at the proximal and distal ends.

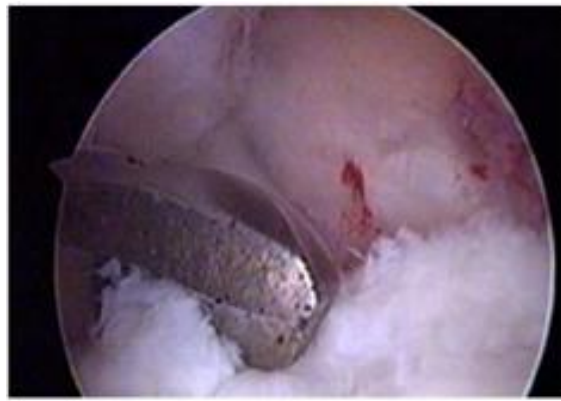
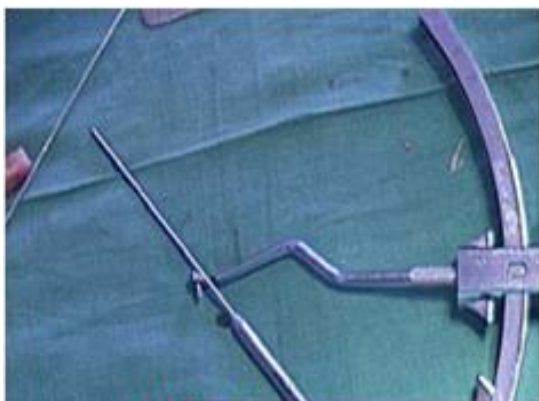


Fig 3: With Double bundle method graft preparation

Tunnel preparation

Arthroscopic examination of knee performed and intraarticular pathology identified dealt with and notchplasty was performed to adequately visualize the over-the-top position on femoral side with femoral tunnel at 11 o'clock and 9:30 (right) or 1 o'clock and 2:30 (left) for anteromedial and postero lateral bundles respectively. Femoral tunnel for

Postero lateral bundle made with accessory anteromedial portal and for Anteromedial bundle through transtibial approach. A posterior cruciate ligament-referencing tibial guide set at 55° was used to place a tibial guide pin into the posterior half of the tibial anterior cruciate ligament attachment site.



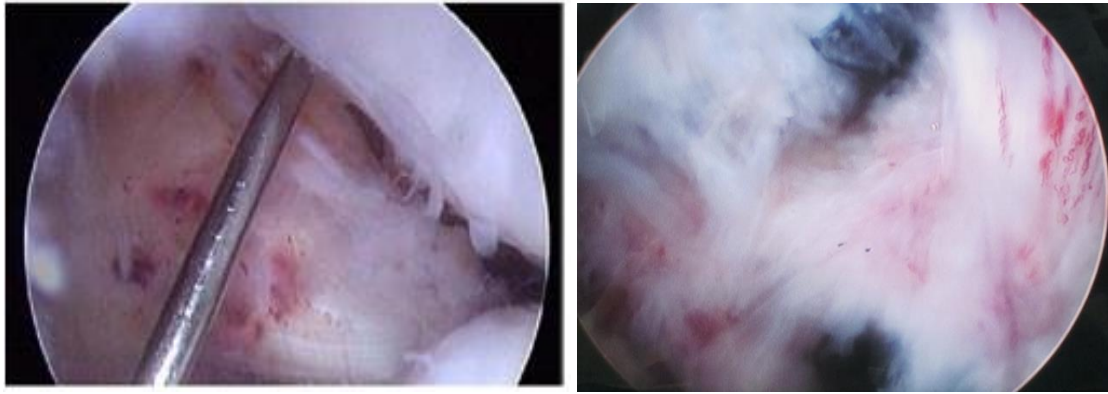


Fig 4: With Double bundle tunnel preparation

Graft fixation

Through tibial tunnel PL bundle and AM bundle grafts passed and pulled simultaneously. Through accessory anteromedial portal soft threaded interference screws placed intra

articularly on femoral end of graft anterolaterally for PL and AM bundles and tibial screw posterior to graft at the tibial end. Knee was examined for laxity. Wound closed in layers and compression bandage was applied.



Fig 5: With Double bundle graft placement

Post-operative protocol

First 1-3 weeks

Wound care and swelling control with Compression bandage was applied for every patient. Isometric exercises for Quadriceps and hip abduction strengthening were carried out. Ice packs were advised to be applied for 4 -5 times a day for swelling control as required. Knee was kept in extension with pillows kept under heel and knee presses against bed carried out to achieve full extension. Sutures removed on 10th post-operative day. Knee was allowed to bend up to 90 degrees as pain permits with hinged knee brace. Weight bearing permitted as pain permits with or without elbow crutches.

Rehabilitation protocol

Goals of rehabilitation are pain and swelling control, maintaining range of motion, protection of anterior cruciate ligament graft, building hamstring and quadriceps muscles and regaining near normal strength and return to pre-injury level of activity.

3-6 weeks

Ice packs were advised to be applied for 4 -5 times a day for swelling control as required. Isometric quadriceps exercises were continued and Hamstring strengthening exercises were started with 2kgs of weight and gradually increasing at increments of 1kg per week till 6 weeks. Static cycling exercises were started. Active exercises to improve range of motion continued.

7-12 weeks

Quadriceps strengthening exercises started with 1kg weight

gradually increased weekly upto 4 kgs of weight and Hamstring strengthening exercises until 12 kgs of weight was reached. Static cycling exercises were continued with increasing resistance.

13 weeks-6 months

Quadriceps strengthening exercises at 4 -6 kgs and Hamstring strengthening at 12 kgs was continued daily along with static cycling exercises till 6 months. Proprioceptive training exercises and running in straight line was encouraged. Squatting, cutting and pivoting were avoided.

6-12 months

Gradually depending on satisfactory completion of rehabilitation program patient allowed initially to return to noncontact or limited contact sports followed by gradual return to contact sports with caution and further injury prevention and avoidance training.

End point evaluation

For final end point statistic evaluation, all patients were reviewed and analyzed at the end of 3 months postoperatively. Postoperatively Patients were followed to minimum of 7 years once yearly. Assessment includes preoperative, Intraoperative findings and post-operative subjective assessment scores and examination findings, pre and post operatively the Lysholm score, Tegner activity level, and International Knee Documentation Committee (IKDC) evaluation system were used as scoring systems. Patients were evaluated using the IKDC score according to the 2000 IKDC Knee Examination

Form. Post-operative activities of daily living and pain assessed by visual analog scale. The manual Lachman test (graded as 0, +1, +2, +3) and anterior drawer tests were used for the assessment of laxity.

Results

Most of the patients present in the range of 15 to 40 years, The average age was 27.6 years.

Out of 60 patients followed most of them were men. Right side anterior cruciate ligament deficiency was seen in 38 (63.33%) patients and 22 (36.67%) had left side involvement. Most of the patient presenting compliant was knee pain following valgus external rotation of leg. Time period from

injury to surgical intervention ranges between 1.5 months to 120 months with mean of 17.08 months and median of 10 months

Pre-Operative Evaluation Data

International knee documentation committee score range was 33.33-64.37. The mean value was 55.25, Tegner's scores were between 2-9 with mean value 4.5 suggestive of average activity levels of moderately heavy labour, Lysholm scores were between 20-83 with mean value was 52.8. Function before injury recorded on visual analog scale all patients scored 10/10. Function after injury recorded on visual analog scale range was 2-9 with mean value was 6.53.

Table 1: Statistical Analysis

	Pre-operative status	Post op 3 months with single bundle	Post op 3 months with double bundle
IDKC score	55.25	78.08	75.62
Tegners' scores	4.5	5.86	5.8
Lysholm score	52.8	82.8	83.4
Function VAS	6.53	8.6	9

Further follow ups scores didn't differ much in five year follow up.

Other complications

Overall other complications noted were anterior knee pain in 2 patients, pain at terminal extension present in 2 patients, sensory deficit in 1 patient and early infection in 1 patient which subsided with antibiotics.

In single bundle group anterior knee pain was seen in 2

patients and pain at terminal 10 degrees of extension seen in one patient. In Double bundle group early infection seen in one patient in the form of swelling, local warmth and mild fever, which was treated with intravenous antibiotics, pain at terminal 10 degrees of extension seen in one patient and sensory deficit was seen in one patient.

Table 2: Score comparison

Post Op Scores		SB	DB	Significance
International knee documentation committee	Pre op vs post op	23.66 P<0.001(S)	15.18 P<0.001(S)	P=0.706 (NS)
Activities of daily living	Pre op vs post op	10.04 P=0.004(S)	15.63 P<0.001(S)	P=0.417 (NS)
Tegners score	Pre op vs post op	1.44 P=0.241(NS)	10.25 P=0.003(S)	F=0.02 P=0.9(NS)
Lysholm score	Pre op vs post op	33.1 P<0.001(S)	21.6 P<0.001(S)	0.01 P=0.924(NS)
Lachman test	One way	F=3.57 P=0.069		
Hop test	Can't be done	86.2	85.86	F=0.01 P=0.911(NS)



Fig 6: post-operative x-rays of double and single bundle ACL reconstruction

On comparison with the study done in the past for discussion

Table 3: Comparisons with other study

Variable	Alberto Gobbi <i>et al.</i> (2012)	Our Study (Birrd Hospital)
No of patients	60	60
Gender Males/females	SB-15/15	SB-28/2
	DB-18/12	DB-30/0
Age (average)	SB-31.9	SB-26.9
	DB-28.9	DB-28.2
Side involved Right/left	SB-12/18	SB-22/8
	DB-18/12	DB-16/14

Surgical method	SB-30	SB-30
	DB-30	DB-30
Follow-up	3 years	7 years
Meniscal lesions	SB-10	SB-8
	DB-8	DB-5
1 ⁰ -2 ⁰ chondropathy	SB-2	SB-1
	DB-2	DB-2
IKDC subjective	Pre op- SB-41.5	Pre op- SB-53.73
	DB-43.0	DB- 57.16
	Post op- SB-89.4	Post op- SB- 78.08
	DB-88.0	DB- 75.62
IKDC objective	Post op- SB- 20A/10B	Post op – SB- 10A/5B
	DB-21A/9B	DB- 7A/7B/1C
Tegner's score	Pre op- SB-2.0	Pre op- SB-5.0
	DB-2.3	DB-4
	Post op- SB-6.73	Post op- SB-5.86
	DB-7.10	DB-5.8
Lysholm score	Pre op- SB-42.4	Pre op- SB-49.73
	DB-40.4	DB-56.13
	Post op- SB-93.3	Post op- SB-82.8
	DB-92.8	DB-83.4
Range of motion	Post op- SB- 0-135.5 ⁰	Post op- SB-137.3 ⁰
	DB- 0-134.5 ⁰	DB-135.3 ⁰
Pivot shift (normal/glide +)	SB-25/5	SB-12/3
	DB-26/4	DB-14/1

In our study overall post-operative results are satisfactory within each group in terms of international knee documentation committee subjective scores, Lysholm score, activities of daily living by visual analog scale and Tegner's activity levels scores, when compared to pre-operative scores. This study shows no statistically significant difference in single leg hop test between two groups. However, patients in either group failed to reach pre-injury activities of daily living in reference to visual analogue scale. Overall, 80% of the people in either group scored normal or near normal and 20% of people scored abnormal or severely abnormal IKDC grades. In the end we conclude No clear cut advantage for either Single bundle technique or Double bundle technique of anterior cruciate ligament reconstruction in terms of post-operative outcomes or complications.

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